UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2019**

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____**

Commission file number: 001-16133

DELCATH SYSTEMS, INC.

Delaware	**06-1245881**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1633 Broadway, Suite 22C New York, NY	**10019**
(Address of principal executive offices)	(Zip Code)

212-489-2100
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock	DCTH	OTCQB

Securities registered pursuant to Section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting common stock held by non-affiliates of the registrant, based on the closing sale price on the OTC of $84.00 per share, was $2,189,040 as of June 30, 2019.

At March 25, 2020, the registrant had outstanding 72,773 shares of common stock, par value $0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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Disclosure Regarding Forward-Looking Statements

This Annual Report on Form 10-K for the period ended December 31, 2019 contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "could," "would," "will," "may," "can," "continue," "potential," "should," and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this Annual Report on Form 10-K for the period ending December 31, 2019 that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act and Section 27A of the Securities Act of 1933, as amended, or the Securities Act. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this Annual Report on Form 10-K for the fiscal year ended December 31, 2019 in Item 1A under "Risk Factors" and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- our ability to successfully commercialize CHEMOSAT and Melphalan/HDS, generate revenue and successfully obtain reimbursement for the procedure and System;
- the progress and results of our research and development programs;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of the system and enter into supplier contracts;
- our ability to successfully manufacture CHEMOSAT and Melphalan/HDS;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and
- our estimates of potential market opportunities and our ability to successfully realize these opportunities.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect the occurrence of unanticipated events.

Item 1. Business.

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the "Company", "Delcath", "Delcath Systems", "we", "our", and "us" refers to Delcath Systems, Inc., a Delaware corporation, incorporated in August 1988, and all entities included in our consolidated financial statements. Our corporate offices are located at 1633 Broadway, Suite 22C, New York, New York 10019. Our telephone number is (212) 489-2100 and our internet address is www.delcath.com.

Company Overview

We are an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our lead product candidate, Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System, or Melphalan/HDS, is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, Melphalan/HDS is approved for sale under the trade name Delcath CHEMOSAT ® Hepatic Delivery System for Melphalan, or CHEMOSAT.

Our primary research focus is on ocular melanoma liver metastases, or mOM, and intrahepatic cholangiocarcinoma, or ICC, a type of primary liver cancer, as well as certain other cancers that are metastatic to the liver. We believe that the disease states we are investigating are unmet medical needs that represent significant market opportunities.

We are investigating the objective response rate of Melphalan/HDS in patients with mOM in our FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma, or the FOCUS Trial, a global registration clinical trial. For information on the FOCUS Trial, see "Business—Clinical Development Program—The FOCUS Trial".

We are also conducting the ALIGN Trial, a global Phase 3 clinical trial of Melphalan/HDS in patients with ICC, or the ALIGN Trial. For information on the ALIGN Trial, see "Business—Clinical Development Program—The ALIGN Trial" below.

In addition to the FOCUS Trial and the ALIGN Trial, our commercial development plan also includes a registry for CHEMOSAT cases performed in Europe and sponsorship of select investigator-initiated trials, or IITs.

In the United States, Melphalan/HDS is considered a combination drug and device product and is regulated as a drug by the United States Food and Drug Administration, or the FDA. The FDA has granted us six orphan drug designations, including three orphan designations for the potential use of the drug melphalan for the treatment of patients with mOM, hepatocellular carcinoma and ICC. Melphalan/HDS has not been approved for sale in the United States.

In Europe, our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are commercializing the CHEMOSAT system in select markets in the United Kingdom and the European Union, or EU, where we believe the prospect of securing reimbursement coverage for the use of CHEMOSAT is strongest.

Cancers in the Liver—A Significant Unmet Need

According to the American Cancer Society's, or ACS, *Cancer Facts & Figures 2018* report, cancer is the second leading cause of death in the United States, with an estimated 609,640 deaths and 1.7 million new cases were expected to be diagnosed in 2018. Cancer is one of the leading causes of death worldwide, accounting for approximately 9.6 million deaths and 18.1 million new cases in 2018 according to GLOBOCAN, the database of the International Association of Cancer Registries. The financial burden of cancer is enormous for patients, their families and society. The Agency for Healthcare Quality and Research estimates that the direct medical costs (total of all healthcare expenditures) for cancer in the United States in 2015 was $80.2 billion. The liver is often the life-limiting organ for cancer patients and cancer that spreads to the liver is one of the leading causes of cancer death. Cancer that begins in one area of the body often metastasizes to the liver. Patient prognosis is generally poor once cancer has spread to the liver. Consequently, cancers of the liver remain a major unmet medical need globally.

Liver Cancers—Incidence and Mortality

Cancers of the liver consist of primary liver cancer and metastatic liver cancer. Primary liver cancer (hepatocellular carcinoma, or HCC, including ICC) originates in the liver or biliary tissue and is particularly prevalent in populations where the primary risk factors for the disease, such as hepatitis-B, hepatitis-C, high levels of alcohol consumption, aflatoxin, cigarette smoking and exposure to industrial pollutants, are present. Metastatic liver cancer, also called liver metastasis, or secondary liver cancer, results from the spread or "metastases" of a primary cancer into the liver. These metastases often continue to grow even after the primary cancer in another part of the body has been removed. Given the vital biological functions of the liver, including processing nutrients from food and filtering toxins from the blood, it is not uncommon for metastases to settle in the liver. In many cases patients die not as a result of their primary cancer, but from the tumors that metastasize to their liver. In the United States, metastatic liver disease is more prevalent than primary liver cancer.

There are few effective treatment options for certain cancers in the liver. Traditional treatment options include surgery, systemic chemotherapy, immunotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. We believe that CHEMOSAT and Melphalan/HDS represent a potentially important advancement in regional therapy for primary liver cancer and certain other cancers metastatic to the liver and are uniquely positioned to treat the entire liver either as a standalone therapy or as a complement to other therapies.

Ocular Melanoma

Ocular melanoma frequently metastasizes to the liver. Based on third party research that we commissioned in 2018, we estimate that approximately 3,700-4,700 cases of ocular melanoma are diagnosed in the United States and Europe annually, and that approximately 50-55% of these patients will develop metastatic disease. Of metastatic cases of ocular melanoma, approximately 90% of patients will develop liver involvement. According to Lane et al., *JAMA Ophthalmol*. 2018 Sep 1;136(9):981-98, once ocular melanoma has spread to the liver, median overall survival for these patients is generally 3.9 months (untreated) to 6.3 months (treated). There is no one standard of care for patients with ocular melanoma liver metastases. Based on the research conducted in 2018, we estimate that approximately 1,400-2,150 patients with ocular melanoma liver metastases in the United States, the United Kingdom and the EU may be eligible for treatment with the Melphalan/HDS annually. Based on our reimbursement experience with CHEMOSAT, we estimate

the annual addressable market for this indication in the United States, the United Kingdom and the EU is approximately $200 million per year.

Intrahepatic Cholangiocarcinoma

Primary liver cancers include HCC and ICC. According to GLOBOCAN, an estimated 78,500 new cases of primary liver cancers are diagnosed in the United States and Europe annually. According to the ACS, approximately 42,810 new cases of these cancers are expected to be diagnosed in the United States in 2020 leading to approximately 30,160 deaths.

ICC is the second most common form of primary liver cancer and according to Wang et al., 2013 J Clin Oncol 31:1188-1195 accounts for 5-30% of primary liver cancers diagnosed in the United States and Europe annually. We believe that 90% of ICC patients are not candidates for surgical resection, and that approximately 20-30% of these may be candidates for certain focal interventions. According to third party research that we commissioned in 2018 we estimate that approximately 11,000 ICC patients in the United States, the United Kingdom and the EU annually could be candidates for treatment with Melphalan/HDS. Based on our reimbursement experience with CHEMOSAT, we estimate the annual addressable market for this indication in the United States, the United Kingdom and the EU is approximately $825 million per year.

According to the ACS, the overall five-year survival rate for primary liver cancers in the United States is approximately 18%. For patients diagnosed with a localized stage of disease, the ACS estimates 5-year survival at 33%.

About CHEMOSAT and Melphalan/HDS

Our product administers concentrated regional chemotherapy to the liver. This “whole organ” therapy is performed by isolating the circulatory system of the liver, infusing the liver with a chemotherapeutic agent, and then filtering the blood prior to returning it to the patient’s circulatory system. During the procedure, known as percutaneous hepatic perfusion, PHP ®, or PHP therapy, three catheters are placed percutaneously through standard interventional radiology techniques. The catheters temporarily isolate the liver from the body’s circulatory system, allow administration of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and collect blood exiting the liver for filtration by our proprietary filters. The filters absorb the chemotherapeutic agent in the blood, thereby reducing systemic exposure to the drug and related toxic side effects, before the filtered blood is returned to the patient’s circulatory system.

PHP therapy is performed in an interventional radiology suite in approximately two to three hours. Patients remain in an intensive care or step-down unit overnight for observation following the procedure. Treatment with CHEMOSAT and Melphalan/HDS is repeatable, and a new disposable system is used for each treatment. Patients treated in clinical settings are permitted up to six treatments. In commercial treatment settings, patients have received up to eight treatments. In the United States, melphalan hydrochloride for injection will be included as part of the system, if approved. In Europe, the system is sold separately and used in conjunction with melphalan hydrochloride commercially available from a third party. In our clinical trials, melphalan hydrochloride for injection is provided to both European and United States clinical trial sites.

Early development of Melphalan/HDS System—FDA Complete Response Letter

Based on clinical trials conducted using an earlier version of our Melphalan/HDS system, in August 2012 we submitted an NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, seeking FDA approval for use of our Melphalan/HDS system for the percutaneous intra-arterial administration of melphalan hydrochloride for use in the treatment of patients with metastatic melanoma in the liver and, subsequently, amended the application to ocular melanoma metastatic to the liver with an earlier version.

In the Spring of 2013, an Oncologic Drug Advisory Committee, or ODAC panel, convened by the FDA voted 16 to 0, with no abstentions, that the benefits of treatment with the early version of Melphalan/HDS did not outweigh the risks associated with the procedure. A significant portion of FDA’s presentation to the ODAC panel was focused on the FDA’s assessment of treatment related risks, including the analysis of treatment-related deaths that occurred during clinical trials. The FDA also expressed concerns about hypotension, or low blood pressure, during the procedure, length of hospital stay, as well as risks of stroke, heart attack, renal failure, and bone marrow suppression.

In September 2013, the FDA issued a complete response letter, or CRL, relating to our NDA. The FDA issues a CRL after the review of an NDA has been completed and questions remain that preclude approval of the NDA in its current form. The deficiencies identified by FDA in the CRL included, a statement that we had to perform additional “well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS using overall survival as the primary efficacy outcome measure,” and which “demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks.” The FDA also required that the additional clinical trial(s) be

conducted using the product we intended to market, and that certain clinical, clinical pharmacology, human factors and product quality elements be addressed.

In January 2016, we entered into a Special Protocol Assessment agreement, or SPA, with the FDA on the design of a new Phase 3 clinical trial of Melphalan/HDS to treat patients with hepatic dominant ocular melanoma. This SPA represented an agreement with FDA that a specific Phase 3 trial would adequately address objectives that, if met, would support the submission for regulatory approval of Melphalan/HDS. The primary endpoint was overall survival, and secondary endpoints included progression-free survival, overall response rate and quality-of-life measures. In the summer of 2018, we amended the protocol for the trial which, after much discussion regarding improvement of the enrollment rate with FDA, resulted in the trial protocol design becoming a non-randomized, single-arm study with a different primary endpoint (objective response rate), which effectively terminated the SPA.

We believe that the protocol amendments and other procedure refinements instituted during clinical trials and subsequently in commercial treatment usage in Europe, including changes to the way blood pressure is managed and monitored, may help address these procedure related risks. Collection of adequate safety data on all aspects of the procedure is a major focus of the clinical trials in our current clinical development program.

Procedure and Product Refinements

In 2012, we introduced the Generation Two version of the CHEMOSAT system, which offered improved hemofiltration and other device component product enhancements. Reports from treating physicians in both Europe and the United States using the Generation Two CHEMOSAT and Melphalan/HDS have indicated that these product improvements and procedure refinements have improved the safety profile of our product. Since 2017, physicians in Europe and the United States have presented and published the results of research that indicated an improved safety profile by decreasing the percentage of adverse events experienced by treated patients, as well as efficacy in multiple tumor types. Collection of adequate safety data on all aspects of the procedure is a major focus of our clinical trials.

Clinical Development Program

The focus of our clinical development program is to generate clinical data for CHEMOSAT and Melphalan/HDS in various disease states to demonstrate efficacy and validate the safety profile of the current version of the product and treatment procedure. We believe that the improvements we have made to CHEMOSAT and Melphalan/HDS and to the PHP therapy have addressed the adverse event profile and procedure-related risks that led to the issuance of the CRL. Our clinical development program is also designed to support clinical adoption of and reimbursement for CHEMOSAT in Europe, and to support regulatory approvals and reimbursement in various jurisdictions, including the United States.

The FOCUS Trial

In July 2018, we commenced an amended clinical trial of Melphalan/HDS, titled *A Single-arm, Multi-Center, Open-Label Study to Evaluate the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment in Patients with Hepatic-Dominant Ocular Melanoma*, or the FOCUS Trial. Under the revised study protocol, the FOCUS Trial will study a minimum of 80 patients with ocular melanoma metastatic to the liver. The primary endpoint of the FOCUS Trial is objective response rate, or ORR as measured by RECISTv1.1. Secondary endpoints include duration of response, disease control rate, overall survival and progression-free survival. Additional exploratory outcome measures include time to objective response, hepatic progression-free survival, hepatic objective response, and quality of life, safety and other pharmacokinetic measures. Patients previously enrolled in the Melphalan/HDS arm of the original trial will continue to be treated and statistically evaluated as part of the revised FOCUS Trial. The FOCUS Trial is being conducted at approximately 30 sites in the United States and Europe.

The rarity of ocular melanoma, absence of crossover to the experimental trial arm, and the commercial availability of PHP® Therapy in Europe impeded enrollment in this trial under the original protocol. While the revised protocol of the FOCUS Trial was intended to accelerate the completion of patient enrollment, enrollment of patients in this trial was adversely affected by a lack of capital to fund the trial. Enrollment of the required patients has been completed. We expected to announce top-line data from this trial in mid-2020. However, the COVID-19 pandemic has impacted our ability to enroll and treat patients in this trial and to monitor data at our clinical trial sites. As a result, we will not be able to release the top-line data from the FOCUS Trial within the timeframe we had anticipated. Once our clinical trial sites are able to return to normal operating procedures, we will assess the impact and update our expected timing accordingly.

The ALIGN Trial

In April 2018 we initiated a pivotal trial of Melphalan/HDS in patients with ICC, titled *A Randomized, Controlled Study to Compare the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment Given Sequentially Following Cisplatin/Gemcitabine versus Cisplatin/Gemcitabine (Standard of Care) in Patients with Intrahepatic Cholangiocarcinoma*, or the ALIGN Trial. The ALIGN Trial is being conducted under an SPA with the FDA. The ALIGN Trial will study approximately 295 ICC patients at approximately 40 clinical sites in the U.S. and Europe. The primary endpoint of the ALIGN Trial is overall survival, or OS, and secondary and exploratory endpoints include safety, progression-free survival, or PFS, ORR and quality-of-life measures. Under the terms of the SPA agreement for the ALIGN Trial, the pivotal trial design adequately addresses objectives that, if met, would support FDA regulatory requirements for approval of Melphalan/HDS in ICC. However, final determinations for marketing application approval are made by FDA after a complete review of a marketing application and are based on the totality of data in the application.

Although, the first patient was enrolled in the ALIGN Trial in October 2018, we have experienced difficulties enrolling trial subjects under the existing trial protocol because patients that have received standard of care treatment outside of the trial are excluded. We intend to seek FDA approval to amend the trial protocol so that such patients are no longer excluded.

Prior Phase 2 Trials

In 2014 we initiated a Phase 2 clinical trial program in Europe and the United States of Melphalan/HDS in the treatment of HCC and ICC. Due to differences in treatment practice patterns between Europe and the United States, we established separate European and United States trial protocols for the HCC Phase 2 program with different inclusion and exclusion patient selection criteria:

Protocol 201 NCT02406508—Conducted in the United States, this trial was intended to assess the safety and efficacy of Melphalan/HDS followed by sorafenib. This trial was terminated earlier than planned so that we could focus our resources on our ocular melanoma study and is no longer enrolling patients.

Protocol 202 NCT02415036—Conducted in Europe, this trial was intended to assess the safety and efficacy of Melphalan/HDS without sorafenib. The trial was also designed to evaluate overall response rate via mRECIST criteria, progression free survival and to characterize the systemic exposure of melphalan and assess patient quality of life. This trial was terminated earlier than planned so that we could focus our resources on our ocular melanoma study and is no longer enrolling patients.

ICC Cohort—In 2015 we expanded *Protocol 202* to include a cohort of patients with ICC. The trial for this cohort was conducted at the same centers participating in the Phase 2 HCC trial. Enrollment of this cohort was completed in 2017; however, analysis of the data has only recently begun due to resource constraints. We expect the results of this trial to be announced before the end of 2020.

ICC Retrospective Data Collection—We did not proceed with the Phase 2 ICC trial because efficacy data for this indication was obtained from multicenter patient outcomes identified in the retrospective data collection of our commercial ICC cases conducted by our European investigators. These outcomes and observations were discussed with Key Opinion Leaders at a Delcath-organized medical advisory panel meeting and led to the conclusion that PHP therapy does “demonstrate an efficacy signal in ICC and is worthy of full clinical investigation.” Data from the retrospective data collection were published in 2018 in “European Radiology” in a paper titled “Percutaneous Hepatic Perfusion (Chemosaturation) with Melphalan in Patients with Intrahepatic Cholangiocarcinoma: European Multicentre Study on Safety, Short Term Effects and Survival”. Details of the findings from this study are discussed below under “Recent Data Presentations”.

European Clinical Data Generation

In April 2015, we created a prospective patient registry in Europe to collect uniform essential patient safety, efficacy, and QoL information using observational study methods. This registry is intended to gather data in multiple tumor types from commercial cases performed by participating cancer centers in Europe. Registry data is considered to be supportive data and, as such, cannot be used for either registration approval, promotional or competitive claims. However, we believe the patient registry will provide a valuable supportive data repository that contains real-world evidence, from a commercial setting, that can be used to identify further clinical development opportunities, support clinical adoption and reimbursement in Europe.

In addition, we also provide support for a number of IITs.

Recent Data Presentations

In July 2019 results from a single-institution retrospective study conducted by University Hospital of Tubingen in Germany on the use of the Delcath CHEMOSAT® Hepatic Delivery System to treat patients with metastatic ocular melanoma with liver metastases were published in the journal *Cancer Imaging*.

The study, *Chemosaturation with percutaneous hepatic perfusion of melphalan for liver dominant metastatic uveal melanoma: a single center experience*, by Dr. Christoph Artzner, et al, evaluated the safety and efficacy of PHP® therapy in 16 patients with unresectable liver metastases from ocular melanoma treated with CHEMOSAT between June 2015 and December 2018. Tumor response was evaluated following each PHP treatment using Response Evaluation Criteria in Solid Tumors, and serious adverse events, or SAEs, were evaluated using Common Criteria for Adverse Events.

The 16 patients underwent a total of 28 PHP treatments. Results of the study in the 15 evaluable patients showed that after the first PHP treatment, nine patients (60%) had a partial response, or PR, five patients (33%) had stable disease, and one patient (7%) had progressive disease for an initial disease control rate of 93%. Median PFS after the first treatment was 11.1 months. Six patients received a second PHP treatment, three patients received three treatments, and a single patient received six treatments. Median overall survival, or OS, was 27.4 months.

Safety analysis showed that grade three SAEs were observed in 14% of treatments, consisting of anemia, leukopenia and thrombocytopenia. The sole grade four SAE observed was in one patient who suffered a cardiac arrest during the first PHP treatment and was removed from the study. Subsequent evaluation determined that this patient had coronary artery occlusion which was successfully treated. Retrospective evaluation of this patient's pre-procedure imaging revealed signs of coronary artery disease, and investigators subsequently modified their screening procedures for cardiovascular risk factors. Investigators stated that most SAEs were grade one or two and that 5% of the reported grade three and four SAEs required additional intervention.

Investigators concluded that for patients with liver-dominant metastatic uveal melanoma, treatment with PHP Therapy had "observed rates for OS and PFS that exceeded the reported outcomes for traditional systemic treatment." Investigators stated that SAEs were frequent, but most did not require additional intervention, and that care should be taken in patients with suspected coronary heart disease.

In April 2019 results from a prospective Phase 2 study conducted by Leiden University Medical Center, or LUMC, in the Netherlands on the use of CHEMOSAT to treat patients with metastatic ocular melanoma with liver metastases were presented at the European Conference on Interventional Oncology annual meeting.

The LUMC study titled "Percutaneous hepatic perfusion with melphalan in patients with unresectable liver metastases from ocular melanoma using the Delcath System's second-generation hemofiltration system: a prospective phase II study" was conducted by a team led and presented by Dr. Mark Burgmans. The study evaluated 35 patients with unresectable liver metastases from ocular melanoma treated with CHEMOSAT between February 2014 and June 2017. The 35 patients underwent a total of 72 PHP therapy treatments, and tumor response was evaluable in 32 patients. Primary endpoints were overall response, overall survival, and progression free survival. Secondary measures included safety measures and hematologic toxicity.

Results of the study showed that one patient had a complete response and 22 had partial response, for a combined overall response rate of 74.1%. Overall survival was 20.3 months and mean progression free survival was 8.1 months.

Safety analysis showed a total of 14 SAEs were recorded. The hematologic toxicities were in a majority of the cases self-limiting and manageable. The investigators concluded that "PHP Therapy with the Generation Two version of CHEMOSAT is an effective and safe treatment for patients with hepatic metastases from ocular melanoma."

Market Access and Commercial Clinical Adoption

Europe

Our European marketing activities include establishing strategic alliances with partners that include license, supply, sales and marketing arrangements. In December 2018, we entered into a License Agreement, or License, with medac GmbH, or medac, for the commercialization of CHEMOSAT in Europe. Under the terms of the medac License, medac has the exclusive right to sell and market CHEMOSAT in all member states of the EU, Norway, Liechtenstein, Switzerland, and the United Kingdom. Under the medac License, we are entitled to a combination of upfront and success-based milestone payments as well as a fixed transfer price per unit of CHEMOSAT and specified royalties.

Since launching CHEMOSAT in Europe, over 750 commercial treatments have been performed at over 25 European cancer centers. Physicians in Europe have used CHEMOSAT to treat patients with a variety of cancers in the liver, primarily ocular melanoma liver metastases, and other tumor types, including cutaneous melanoma, hepatocellular carcinoma, cholangiocarcinoma, and liver metastases from colorectal cancer, breast, pancreatic and neuroendocrine.

European Reimbursement

A critical driver of utilization growth for CHEMOSAT in Europe is the expansion of reimbursement mechanisms for the procedure in our priority markets. In Europe, there is no centralized pan-European medical device reimbursement body. Reimbursement is administered on a regional and national basis. Medical devices are typically reimbursed under Diagnosis Related Groups, or DRG, as part of a procedure. Prior to obtaining permanent DRG reimbursement codes, in certain jurisdictions, we are actively seeking interim reimbursement from existing mechanisms that include specific interim reimbursement schemes, new technology payment programs as well as existing DRG codes. In most EU countries, the government provides healthcare and controls reimbursement levels. Since the EU has no jurisdiction over patient reimbursement or pricing matters in its member states, the methodologies for determining reimbursement rates and the actual rates may vary by country.

Under the terms of the medac License, medac is required to provide support for reimbursement applications in the European markets covered by our agreement. CHEMOSAT is approved for reimbursement in the United Kingdom and Germany.

Government Regulation

Our products are subject to extensive and rigorous government regulation by foreign regulatory agencies and the FDA. Foreign regulatory agencies, the FDA and comparable regulatory agencies in state and local jurisdictions impose extensive requirements upon the clinical development, pre-market clearance and approval, manufacturing, labeling, marketing, advertising and promotion, pricing, storage and distribution of pharmaceutical and medical device products. Failure to comply with applicable foreign regulatory agency or FDA requirements may result in Warning Letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

United States Regulatory Environment

In the United States, the FDA regulates drug and device products under the FDCA, and its implementing regulations. Melphalan/HDS is subject to regulation as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of its primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of the Melphalan/HDS, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research, has primary jurisdiction over its pre-market development and review.

The process required by the FDA before drug product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated periodically, but at least annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced and tested to assess compliance with current good manufacturing practice, or cGMP, regulations; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted on a timely basis, if at all.

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent

institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the United States IND are required in the EU and other jurisdictions in which we may conduct clinical trials.

Clinical Trials

For purposes of NDA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

- Phase 1 Clinical Trials. Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism and excretion, typically in healthy humans, but in some cases in patients.
- Phase 2 Clinical Trials. Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 Clinical Trials. These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.
- Phase 4 Clinical Trials. The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase 4 clinical trials.

Sponsors of clinical trials may submit proposals for the design, execution, and analysis for their pivotal trials under a SPA. A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in an NDA, without the sponsor’s agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins.

Prior to initiating our currently ongoing Phase 3 clinical trial(s), we submitted a proposal for the design, execution and analysis under a SPA.

New Drug Applications

The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which may be waived in certain circumstances. Once the submission has been accepted for filing, the FDA’s goal is to review applications within ten months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. For new oncology products, the FDA will often solicit an opinion from an ODAC, a panel of expert authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions. The ODAC panel reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer, and makes appropriate recommendations to the Commissioner of Food and Drugs. The FDA is not bound by the recommendation of an advisory committee. The FDA may deny approval of an NDA by issuing a Complete Response Letter, or CRL, if the applicable regulatory criteria are not satisfied. A CRL may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may be contingent on a Risk Evaluation and Mitigation Strategy, or REMS, that limits the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product

reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

There are three primary regulatory pathways for a New Drug Application under Section 505 of the FDCA: Section 505 (b)(1), Section 505 (b)(2) and Section 505(j). A Section 505 (b)(1) application is used for approval of a new drug (for clinical use) whose active ingredients have not been previously approved. A Section 505 (b)(2) application is used for a new drug that relies on data not developed by the applicant. Section 505(b)(2) of the FDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely in part upon the FDA's findings of safety and effectiveness for previously approved products. Section 505(j) application, also known as an abbreviated NDA, is used for a generic version of a drug that has already been approved.

Orphan Drug Exclusivity

Some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Pursuant to the Orphan Drug Act, the FDA grants orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The orphan designation is granted for a combination of a drug entity and an indication and therefore it can be granted for an existing drug with a new (orphan) indication. Applications are made to the Office of Orphan Products Development at the FDA and a decision or request for more information is rendered in 60 days. NDAs for designated orphan drugs are exempt from user fees, obtain additional clinical protocol assistance, are eligible for tax credits up to 50% of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment. Exclusivity begins on the date that the marketing application is approved by the FDA for the designated orphan drug, and an orphan designation does not limit the use of that drug in other applications outside the approved designation in either a commercial or investigational setting.

We have received six orphan drug designations: two for melphalan for the treatment of patients with cutaneous melanoma, as well as patients with ocular melanoma; one for melphalan for the treatment of patients with neuroendocrine tumors; one for doxorubicin for the treatment of patients with primary liver cancer; one for melphalan for the treatment of HCC; and one for melphalan for the treatment of cholangiocarcinoma, which includes ICC.

The granting of orphan drug designations does not mean that the FDA has approved a new drug. Companies must still pursue the rigorous development and approval process that requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted at all, or on a timely basis.

Other Regulatory Requirements

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Untitled Letters or Warning Letters that could cause us or our third-party manufacturers to modify certain activities. A Form 483 Notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. In addition to Form 483 Notices and Untitled Letters or Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may require us to recall our products from distribution or withdraw any potential approvals of an NDA for that product.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us

to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, in particular in oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

European Regulatory Environment

In the EU, the CHEMOSAT system is subject to regulation as a medical device. The EU is composed of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein. Under the EU Medical Devices Directive (Directive No 93/42/ECC of 14 June 1993, as last amended), drug delivery products such as the CHEMOSAT system is governed by the EU laws on pharmaceutical products only if they are (i) placed on the market in such a way that the device and the pharmaceutical product form a single integral unit which is intended exclusively for use in the given combination, and (ii) the product is not reusable. In such cases, the drug delivery product is governed by the EU Code on Medicinal Products for Human Use (Directive 2001/83/EC, as last amended), while the essential requirements of the EU Medical Devices Directive apply to the safety and performance-related device features of the product. Because we do not intend to place the CHEMOSAT system on the EU market as a single integral unit with melphalan, the product is governed solely by the EU Medical Devices Directive, while the separately marketed drug is governed by the EU Code relating to Medicinal Products for Human Use and other EU legislation applicable to drugs for human use.

Before we may commercialize a medical device in the EU, we must comply with the essential requirements of the EU Medical Devices Directive. Compliance with these requirements entitles a manufacturer to affix a CE conformity mark, without which the products cannot be commercialized in the EU. To demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. In April 2011, we obtained authorization to affix a CE Mark for the Generation One CHEMOSAT system and began European commercialization with this version of the CHEMOSAT system in early 2012. In April 2012, the Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT system, and since this time all procedures in Europe have been performed with this version of the system.

The Medical Devices Directive establishes a classification system placing devices into Class I, IIa, IIb, or III, depending on the risks and characteristics of the medical device. For certain types of low risk medical devices (i.e., Class I devices which are non-sterile and do not have a measuring function), the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directives. Other devices are subject to a conformity assessment procedure requiring the intervention of a Notified Body, which is an organization designated by a Member State of the EU to conduct conformity assessments.

CHEMOSAT is regulated as a Class IIb medical device. As a Class IIb medical device, the Notified Body is not required to carry out an examination of the product's design dossier as part of its conformity assessment prior to commercialization. The Company must continue to comply with the essential requirements of the EU Medical Devices Directive (Directive 93/42 EC) and is subject to a conformity assessment procedure requiring the intervention of a Notified Body. The conformity assessment procedure for Class IIb medical devices requires the manufacturer to apply for the assessment of its quality system for the design, manufacture and inspection of its medical devices by a Notified Body. The Notified Body will audit the system to determine whether it conforms to the provisions of the Medical Devices Directive. If the Notified Body's assessment is favorable, it will issue a Full Quality Assurance Certificate, which enables the manufacturer to draw a Declaration of Conformity and affix the CE mark to the medical devices covered by the assessment. Thereafter, the Notified Body will carry out periodic audits to ensure that the approved quality system is applied by the manufacturer.

A manufacturer without a registered place of business in a Member State of the EU which places a medical device on the market under its own name must designate an Authorized Representative established in the EU who can act before, and be addressed by, the Competent Authorities on the manufacturer's behalf with regard to the manufacturer's obligations under the EU Medical Devices Directive. We appointed such a representative prior to establishing our infrastructure in the EU. With the Delcath Systems Ltd. infrastructure now firmly in place, the Authorized Representative responsibilities have been formally transferred internally and there is no longer a need for a third-party representative.

In the EU, we must also comply with the Medical Device Vigilance System, which is designed to improve the protection of health and safety of patients, users and others by reducing the likelihood of recurrence of incidents related to the use of a medical device. Under this system, incidents are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. When a medical device is suspected to be a

contributory cause of an incident, its manufacturer or authorized representative in the EU must report it to the Competent Authority of the Member State where the incident occurred. Incidents are generally investigated by the manufacturer. The manufacturer's investigation is monitored by the Competent Authority, which may intervene, or initiate an independent investigation if considered appropriate. An investigation may conclude in the adoption of a Field Safety Corrective Action, or FSCA. An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include device recall, modification exchange and destruction.

FSCAs must be notified by the manufacturer or its authorized representative to its customers and/or the end users of the medical device via a Field Safety Notice.

In the EU, the off-label promotion of a pharmaceutical product is strictly prohibited under the EU Community Code on Medicinal Products, which provides that all information provided within the context of the promotion of a drug must comply with the information contained in its approved summary of product characteristics. Our product instructions and indication reference the chemotherapeutic agent melphalan hydrochloride. However, no melphalan labels in the EU reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the CHEMOSAT system and must use melphalan independently at their discretion.

In the EU, the advertising and promotion of our products is also subject to EU Member States laws implementing the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, as well as other EU Member State legislation governing the advertising and promotion of medical devices. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Failure to comply with the EU Member State laws implementing the Medical Devices Directive, with the EU and EU Member State laws on the promotion of medicinal products or with other applicable regulatory requirements can result in enforcement action by the EU Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

The European Commission recently reviewed the Medical Device Directive legislative framework and promulgated REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. This new Medical Device Regulation became effective on May 25, 2017, marking the start of a 3-year transition period for manufacturers selling medical device in Europe to comply with the new medical device regulation, or MDR, which governs all facets of medical devices. The transition task is highly complex and touches every aspect of product development, manufacturing production, distribution and post marketing evaluation.

Effectively addressing these changes will require a complete review of our device operations to determine what is necessary to comply. We do not believe the MDR regulatory changes will impact our business at this time, though implementation of the medical device legislation may adversely affect our business, financial condition and results of operations or restrict our operations.

Other International Regulations

We continue to evaluate commercial opportunities in select markets when resources are available and at an appropriate time.

Intellectual Property

Our success depends in part on our ability to obtain patents and trademarks, maintain trade secret and know-how protection, enforce our proprietary rights against infringers, and operate without infringing on the proprietary rights of third parties. Because of the length of time and expense associated with developing new products and bringing them through the regulatory approval process, the health care industry places considerable emphasis on obtaining patent protection and maintaining trade secret protection for new technologies, products, processes, know-how, and methods. We hold rights in eight U.S. utility patents, one U.S. design patent, five pending U.S. utility patent applications, six issued foreign counterpart utility patents (including the validation of a European
patent directed to our filter apparatus in eight European countries, six issued foreign counterpart design patents, and eight pending foreign counterpart patent applications. In July 2017, a patent directed to our chemotherapy filtration system was issued by the U.S. Patent and Trademark Office. In October 2018 and February 2019 patents directed to our chemotherapy filtration system and a method of using our filter and frame apparatus were issued by the United States Patent and Trademark Office. A Notice of Allowance was obtained from the United States Patent and Trademark Office for the patent application entitled "Apparatus For Removing Chemotherapy Compounds from Blood" with allowed claims to a kit of parts capable of being assembled for delivering a small

molecule chemotherapeutic agent to a subject. The allowed claims are directed to CHEMOSAT. A Hong Kong patent directed to our Filter and Frame Apparatus was issued in March of 2018. A European patent was granted for our chemotherapy filtration system in November 2018 and a European patent application directed to a method of using our filter and frame apparatus was granted in April 2019 by the European Patent Office.

When appropriate, we actively pursue protection of our proprietary products, technologies, processes, and methods by filing United States and international patent and trademark applications. We seek to pursue additional patent protection for technology invented through research and development, manufacturing, and clinical use of the CHEMOSAT and Melphalan/HDS that will enable us to expand our patent portfolio around advances to our current systems, technology, and methods for our current applications as well as beyond the treatment of cancers in the liver.

There can be no assurance that the pending patent applications will result in the issuance of patents, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or provide us with a competitive advantage.

To maintain our proprietary position, we also rely on trade secrets and proprietary technological experience to protect proprietary manufacturing processes, technology, and know-how relating to our business. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. In addition, we also seek to maintain our trade secrets through maintenance of the physical security of the premises where our trade secrets are located. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets and proprietary knowledge.

In certain circumstances, United States patent law allows for the extension of a patent’s duration for a period of up to five years after FDA approval. We intend to seek extension for one of our patents after FDA approval if it has not expired prior to the date of approval. In addition to our proprietary protections, the FDA has granted us six orphan drug designations that provide us a seven-year period of exclusive marketing beginning on the date that our NDA is approved by the FDA for the designated orphan drug. While the exclusivity only applies to the indication for which the drug has been approved, we believe that this exclusivity will provide us with added protection once commercialization of an orphan drug designated product begins.

There has been and continues to be substantial litigation regarding patent and other intellectual property rights in the pharmaceutical and medical device areas. If a third party asserts a claim against us, we may be forced to expend significant time and money defending such actions and an adverse determination in any patent litigation could subject us to significant liabilities to third parties, require us to redesign our product, require us to seek licenses from third parties, and, if licenses are not available, prevent us from manufacturing, selling or using our system. Additionally, we plan to enforce our intellectual property rights vigorously and may find it necessary to initiate litigation to enforce our patent rights or to protect our trade secrets or know-how. Patent litigation can be costly and time consuming and there can be no assurance that the outcome will be favorable to us.

Competition

The healthcare industry is characterized by extensive research, rapid technological progress and significant competition from numerous healthcare companies and academic institutions. Competition in the cancer treatment industry is intense. We believe that the primary competitive factors for products addressing cancer include safety, efficacy, ease of use, reliability and price. We also believe that physician relationships, especially relationships with leaders in the medical and surgical oncology communities, are important competitive factors. We also believe that the current global economic conditions and new healthcare reforms could put competitive pressure on us, including reduced selling prices and potential reimbursement rates, and overall procedure rates. Certain markets in Europe are experiencing the effects of continued economic weakness, which is affecting healthcare budgets and reimbursement.

CHEMOSAT competes and, if approved by the FDA Melphalan/HDS will compete, with all forms of liver cancer treatments, including surgery, systemic chemotherapy, focal therapies and palliative care. In the disease states we are targeting there are also numerous clinical trials sponsored by third-parties, which can compete for potential patients in the near term and may ultimately lead to new competitive therapies.

For ocular melanoma liver metastases, there are currently no approved or effective treatment options, and patients are generally treated with a variety of local and regional techniques. There are numerous companies developing and marketing devices for the performance of focal therapies, including Boston Scientific Corporation, the Covidien Products division of Medtronic plc, Merit Medical Systems, Inc., Celenova BioSciences Inc., Sirtex Medical Limited, AngioDynamics, Inc., and many others.

For ICC, gemcitabine plus cisplatin remains the standard of care for the treatment of ICC in patients who are not candidates for surgery.

Several therapies have been recently approved for unresectable or metastatic cutaneous melanoma, which may encompass liver metastases. Dabrafenib (Tafinlar™, GlaxoSmithKline plc), is indicated as single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation, and in combination with trametinib in unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Furthermore, trametinib (MEKINIST™, GlaxoSmithKline plc) is indicated as single agent (in addition to in combination with dabrafinib) for treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Previously approved melanoma therapies such as the biologic ipilimumab (Yervoy™, Bristol Myers Squibb Company) and the B-RAF targeted drug vemurafenib (Zelboraf™, Genentech, Inc.) may also make up the competitive landscape for the treatment of metastatic liver disease.

Many of these treatments are approved in Europe and other global markets.

Many of our competitors have substantially greater financial, technological, research and development, marketing and personnel resources. In addition, some of our competitors have considerable experience in conducting clinical trials, regulatory, manufacturing and commercialization capabilities. Our competitors may develop alternative treatment methods, or achieve earlier product development, in which case the likelihood of us achieving meaningful revenues or profitability will be substantially reduced.

Manufacturing and Quality Assurance

We manufacture certain critical medical device components including our proprietary filter media and assemble and package the CHEMOSAT and Melphalan/HDS at our facility in Queensbury, New York. We have established our European headquarters and distribution facility in Galway, Ireland where we conduct final manufacturing, processing and assembly. We use third-parties to manufacture some components of the CHEMOSAT and Melphalan/HDS. The CHEMOSAT and Melphalan/HDS and its components must be manufactured and sterilized in accordance with approved manufacturing and pre-determined performance specifications. In addition, certain components will require sterilization prior to distribution and we use third-party vendors to perform the sterilization process.

We are required to comply with the FDA's cGMP regulations and international quality system regulations including those established by the International Standards Organization (ISO) with respect to products sold in the EU. We are required to maintain ISO 13485 certification for medical devices to be sold in the EU, which requires, among other items, an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. Our facilities are ISO 13485:2016 certified.

Employees

As of March 25, 2020, we had approximately 33 full time employees located in the United States and in Europe. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We believe our relationship with our employees is good.

Item 1A. Risk Factors

An investment in our securities involve a high degree of risk. You should carefully consider the risks described below, together with the financial and other information contained in this annual report, before you decide to purchase our securities. If any of the following risks actually occurs, our business, financial condition, results of operations, cash flows and prospects could be materially and adversely affected. In that event, the trading price of our common stock and the market value of the securities offered hereby could decline, and you may lose all or part of your investment.

Risks Related to Our Business and Financial Condition

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm issued a report dated March 25, 2020 in connection with the audit of our financial statements as of December 31, 2019, which includes an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. In addition, the notes to our financial statements for the year ended December 31, 2019, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 25, 2020, contain a disclosure describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any commercialization efforts. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we are not able to continue as a going concern, it is likely that holders of our common stock will lose all of their investment.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. We received a complete response letter from the FDA declining to approve our existing New Drug Application, or NDA, in its current form.

Preclinical testing and clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. Drug development is very risky, and it takes several years to complete clinical trials. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator treatment or required prior therapy, clinical outcomes including insufficient efficacy, safety concerns, or our own financial constraints.

In response to our NDA, which we submitted to FDA in August 2012 seeking approval for use of our Melphalan/HDS Kit for the treatment of patients with ocular melanoma of the liver, in September 2013, the FDA denied approval of the NDA in its current form and issued a complete response letter, or CRL. A CRL is issued by the FDA when the review of an NDA is completed, and deficiencies remain that preclude approval of the NDA in its current form. The deficiencies in the CRL included, but were not limited to, a statement that we must perform additional "well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS Kit using overall survival as the primary efficacy outcome measure" and which "demonstrates that the clinical benefits of Melphalan/HDS Kit outweigh its risks." The FDA also required that the additional clinical trial(s) be conducted using the product we intend to market. Prior to conducting additional clinical trials, we were required to satisfy certain other requirements of the CRL, including, but not limited to, product quality testing and human factors information.

We have initiated a pivotal Phase 3 trial in ocular melanoma metastases. We had a SPA agreement with FDA for this study, which was initially designed as a randomized trial with a primary endpoint of overall survival. We subsequently amended the protocol so that the trial is a non-randomized, single-arm study with a primary endpoint of objective response rate. Although the changes to the protocol invalidated the SPA agreement, FDA stated that it would not object to our conducting a study outside of a SPA agreement. However, we will need to justify how the results of the study support a favorable risk-benefit assessment, particularly whether the response rate is sufficient to overcome the toxicity of Melphalan/HDS.

In addition, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial endpoints to support additional indications for Melphalan/HDS and HDS with other drug therapies. In 2014, we initiated a Phase 2 clinical trial with Melphalan/HDS for hepatocellular carcinoma, or HCC, in both the United States and Europe. In 2015, the Phase 2 clinical trial for HCC was expanded to include a cohort of patients with intrahepatic cholangiocarcinoma, a type of primary liver cancer, or ICC. The trial for this cohort was conducted at the same centers participating in the Phase 2 HCC trial. Unfavorable or inconsistent clinical data from clinical trials, including the Phase 2 clinical trial for HCC, the market's perception of these clinical data or FDA's perception of this clinical data, may adversely impact our ability to obtain approval, and our financial condition. Additionally, even if the results of our Phase 2 clinical trial for HCC and ICC are positive, there is a substantial risk that it will fail to have positive results in Phase 3 clinical trials with regard to efficacy, safety or other clinical outcomes and may never obtain regulatory approval.

The Company does not expect to generate significant revenue for the foreseeable future.

Our entire focus has been on developing, commercializing, and obtaining regulatory authorizations and approvals of CHEMOSAT® and Melphalan/HDS and we have only developed this system for the treatment of cancers in the liver. If CHEMOSAT and Melphalan/HDS for the treatment of cancers in the liver fail as commercial products, we have no other products to sell. In addition, since CHEMOSAT currently is approved for commercialization solely in the European Union, or the EU, and limited other jurisdictions, if medac GmbH, or medac, our third-party licensee, is unsuccessful in commercializing the product in the EU and/or if Melphalan/HDS is not approved in the United States and elsewhere, we will have no means of generating revenue. In September 2013, the FDA issued a CRL with respect to our NDA for Melphalan/HDS. A CRL is issued by the FDA when the review of a file is completed and questions remain that preclude approval of the NDA in its then current form. Accordingly, we do not expect to realize any revenues from product sales in the United States in the next few years, if at all. As a result, our revenue sources are, and will remain, extremely limited unless and until our product candidates are approved by the FDA or other additional foreign regulatory agencies and successfully marketed. CHEMOSAT and Melphalan/HDS may not be successful in clinical trials, approved by the FDA or other additional foreign regulatory agency or marketed at any time in the foreseeable future or at all.

Continuing losses may exhaust our capital resources.

As of December 31, 2019, we had $10.0 million in cash and cash equivalents. We have had minimal revenue to date, and have a substantial accumulated deficit, recurring operating losses and negative cash flow. For the years ended December 31, 2019 and 2018, we incurred net losses of approximately $8.9 million and $19.2 million, respectively and expect to continue to incur losses in 2020. To date, we have funded operations through a combination of private placements and public offerings of our securities, including convertible notes. If we continue to incur losses, we may exhaust our capital resources, and as a result may be unable to complete our clinical trials, engage in product development and the regulatory approval process and commercialization of CHEMOSAT and Melphalan/HDS or any other versions of these products. If we are unable to raise capital or generate sufficient revenue, we may not be able to pay our debts when they become due and may have to seek protection under federal bankruptcy law or enter into a receivership.

If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we may not be able to further commercialize CHEMOSAT and Melphalan/HDS, complete our clinical trials or conduct future product development and clinical trials.

We will require additional substantial financing to complete our clinical trial program or seek other approvals, to conduct future development, clinical trials and to further commercialize our product in the EU and any other markets where we may receive approval for our products. If financing is unavailable to make the required payments under these agreements, we could be subject to legal liability and our ability to complete product development projects or clinical trials could be impaired. We do not know if additional financing will be available when needed at all or on acceptable terms. If we are unable to obtain additional financing as needed, we may not be able to further commercialize CHEMOSAT and Melphalan/HDS, obtain regulatory approvals or complete our development projects or clinical trials, which would result in a complete loss of an investment in our securities.

Our liquidity and capital requirements will depend on numerous factors, including:

- clinical studies, including registration trials in ocular melanoma liver metastases and in ICC;
- the timing and costs of our various United States and foreign regulatory filings, obtaining approvals and complying with regulations;
- the timing and costs associated with developing our manufacturing operations;
- the timing of product commercialization activities, including marketing and distribution arrangements overseas;
- the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and
- the impact of competing technological and market developments.

Insufficient funds may require us to curtail or stop our commercialization activities, regulatory submissions or ongoing activities for regulatory approval, research and development and clinical trials, which will significantly limit our potential to generate future revenues.

Risks Related to FDA and Foreign Regulatory Approval

Our failure to obtain, or delays in obtaining, regulatory approvals may have a material adverse effect on our business, financial condition and results of operations.

CHEMOSAT and Melphalan/HDS are subject to extensive and rigorous government regulation by the FDA and other foreign regulatory agencies. The FDA regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical and medical device products. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, subject us to either civil or criminal administrative or judicially-imposed sanctions and/or other penalties.

In the United States, the FDA regulates drug and device products under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Melphalan/HDS is subject to regulation by the FDA as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of the product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of Melphalan/HDS, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research has primary jurisdiction over its pre-market development and review.

We are not permitted to market Melphalan/HDS in the United States unless and until we obtain regulatory approval from the FDA. To market the product in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate. The number and types of preclinical studies and clinical trials that will be required varies depending on the product candidate, the disease or condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause it to repeat or perform additional preclinical studies, CMC studies or clinical trials. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem a product candidate to be adequately safe and effective;
- may determine that the risk: benefit profile is not favorable;
- may not find the data from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;
- may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than we;
- may not approve the manufacturing processes or facilities associated with our product candidates;
- may change approval policies (including with respect to our product candidates' class of drugs) or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Furthermore, we cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may require us to recall our products from distribution or withdraw any potential approvals of an NDA for that product.

Undesirable side effects caused by any product candidate that we develop could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications or cause us to evaluate the future of our development programs. The regulatory review and approval process is lengthy, expensive and inherently uncertain. As part of the U.S. Prescription Drug User Fee Act, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. In August 2012, we submitted the Melphalan/HDS NDA seeking an indication for ocular melanoma liver metastases. In September 2013, the FDA declined to approve the NDA and issued a CRL. The deficiencies in the CRL included, but were not limited to, a statement that we must perform additional "well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS using overall survival as the primary efficacy outcome measure" and which "demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks." The FDA also requires that the additional clinical trial(s) be conducted using the product we intends to market. Prior to conducting additional clinical trials, we must satisfy certain other requirements of the CRL, including, but not limited to, product quality testing and human factors information. However, even if we complete these clinical trials and satisfy all the requirements of the CRL, we may not obtain regulatory approval from the FDA. Continued failure to obtain, or additional delays in obtaining, regulatory approvals may:

- adversely affect the commercialization of the current version of CHEMOSAT and Melphalan/HDS or any products that we develops in the future;

- impose additional costs on us;
- diminish any competitive advantages that may be attained; and
- adversely affect our ability to generate revenues.

We have obtained the right to affix the CE Mark for the CHEMOSAT Hepatic Delivery System as a medical device for the delivery of melphalan. Since we may only promote the device within this specific indication, if physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, our ability to commercialize CHEMOSAT in the EU will be significantly limited.

In the EU, CHEMOSAT is regulated as a Class IIb medical device indicated for the intra-arterial administration of a chemotherapeutic agent, melphalan hydrochloride, to the liver with additional extracorporeal filtration of the venous blood return. Our ability to market and promote CHEMOSAT is limited to this approved indication. To the extent that our promotion of CHEMOSAT is found to be outside the scope of its approved indication, we may be subject to fines or other regulatory action, limiting our ability to commercialize CHEMOSAT in the EU.

We are limited to marketing CHEMOSAT in the EU as a medical device for the delivery of melphalan. If physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, our ability to commercialize CHEMOSAT in the EU will be significantly limited. Our product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EU reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. As a result, the delivery of melphalan with our device may not be within the applicable label with respect to some indications in some Member States of the EU where the drugs are authorized for marketing. Physicians intending to use CHEMOSAT must obtain melphalan separately for use with CHEMOSAT and must use melphalan independently at their discretion. If physicians are unwilling to obtain melphalan separately from CHEMOSAT and/or to prescribe the use of melphalan independently, our sales opportunities in the EU will be significantly limited.

We are subject to significant ongoing regulatory obligations and oversight in the EU and will be subject to such obligations in any other country where we receive marketing authorization or approval.

In April 2012, we obtained the required certification from its European Notified Body, enabling us to complete an EC Declaration of Conformity with the essential requirements of the EU Medical Devices Directive and affix the CE Mark to the Generation Two version of CHEMOSAT. In order to maintain the right to affix the CE Mark in the EU, we are subject to compliance obligations, and any material changes to the approved product, such as manufacturing changes, product improvements or revised labeling, may require further regulatory review. Additionally, we are subject to ongoing audits by our European Notified Body, and the right to affix the CE Mark to the Generation Two version of CHEMOSAT may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product.

To the extent that CHEMOSAT or Melphalan/HDS is approved by the FDA or any other regulatory agency, we will be subject to similar ongoing regulatory obligations and oversight in those countries where approval is obtained. For example, we may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice, or cGMPs, , good clinical practices, or GCPs, , and good laboratory practices, which are regulations and guidelines enforced by the FDA for all products in clinical development, for any pre-clinical or clinical trials that we conducts post-approval. In addition, post-marketing requirements for CHEMOSAT and Melphalan/HDS may include implementation of a risk evaluation and mitigation strategies, or REMS, program to ensure that the benefits of the product outweigh its risks. A REMS may include a medication guide, a patient package insert, a communication plan to healthcare professionals, restrictions on distribution or use and/or other elements to assure safe use of the product.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- refusals or delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved applications;

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;
- fines, Warning Letters or untitled letters, or holds on clinical trials;
- import or export restrictions;
- injunctions or the imposition of civil or criminal penalties;
- restrictions on product administration, requirements for additional clinical trials or changes to product labeling or REMS programs; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

If we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and may not achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

The development and approval process in the United States will take many years, require substantial resources and may never lead to the approval of Melphalan/HDS by the FDA for use in the United States.

We cannot sell or market Melphalan/HDS with melphalan or other chemotherapeutic agents in the United States without prior FDA approval of an NDA for Melphalan/HDS. Although melphalan and other drugs have been approved by the FDA for use as chemotherapeutic agents, regulatory approval is required in the United States for the combined medical device component and drug component and the specific indication, dose and route of administration of melphalan or other chemotherapeutic agents or compounds used in our system. We are seeking approval of Melphalan/HDS for a substantially higher dose of melphalan than prior approved doses of melphalan and such other chemotherapeutic agents or other compounds. We must obtain separate regulatory approvals for Melphalan/HDS with melphalan and every other chemotherapeutic agent or other compound used with the system that we intend to market, and all the manufacturing facilities used to manufacture components or assemble our system must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish to the FDA's satisfaction the product's safety, efficacy, potency and purity for each intended use. The pre-clinical testing and clinical trials of Melphalan/HDS with melphalan or any other chemotherapeutic agent or compound we uses in its system must comply with the regulations of the FDA and other federal, state and local government authorities in the United States. Clinical development is a long, expensive and uncertain process and is subject to delays. We may encounter delays or rejections for various reasons, including our inability to enroll enough patients to complete the clinical trials. Moreover, approval policies or regulations may change. If we do not obtain and maintain regulatory approval for Melphalan/HDS and the use of melphalan or other chemotherapeutic agents, on our business, results of operations, financial condition and prospects would be materially and adversely affected.

In August 2012, we submitted a NDA seeking an indication for ocular melanoma liver metastases for Melphalan/HDS. In September 2013, the FDA issued a CRL indicating that we must perform additional well-controlled randomized trial(s) to establish the safety and efficacy of Melphalan/HDS using overall survival as the primary efficacy outcome measure and which demonstrates that the clinical benefits of Melphalan/HDS outweigh its risks. Our current Phase 3 trial in ocular melanoma liver metastases, the FOCUS Trial, is not randomized and uses a different primary efficacy outcome measure. Failure to obtain FDA approval will have a material adverse effect on our business, financial condition and results of operations.

Even if we obtain regulatory approval for Melphalan/HDS in the United States, our ability to market Melphalan/HDS would be limited to those uses that are approved.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. If the FDA approves an application for Melphalan/HDS, our ability to market and promote Melphalan/HDS would be limited to the approved indication, so even with FDA approval, Melphalan/HDS may only be promoted in this limited market. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use, and FDA approval may otherwise limit our sales practices and our ability to promote, sell and distribute the product. Thus, we may only market Melphalan/HDS, if approved by the FDA, for its approved indication and could be subject to enforcement action for off-label marketing. Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require we to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

If future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market Melphalan/HDS for other indications.

The clinical trial data on our product is limited to specific types of liver cancer. In 2010, we concluded a Phase 3 clinical trial of Melphalan/HDS in patients with metastatic ocular and cutaneous melanoma to the liver and also completed a multi-arm Phase 2 clinical trial of Melphalan/HDS in patients with primary and metastatic melanoma stratified into four arms.

We have initiated an open-label Phase 3 clinical trial in ocular melanoma liver metastases called the FOCUS Trial. We also have initiated a Phase 3 registration trial to treat patients with intrahepatic cholangiocarcinoma (ICC), called the ALIGN trial.

It may take several years to complete the testing of Melphalan/HDS for use in the treatment of these indications, and failure can occur at any stage of development, for many reasons, including:

- any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities;
- pre-clinical or clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;
- the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- we may encounter delays or rejections based on changes in regulatory agency policies during the period in which we are developing a system or the period required for review of any application for regulatory agency approval;
- enrollment in our clinical trials may proceed more slowly than expected;
- our clinical trials may not demonstrate the safety and efficacy of any system or result in marketable products;
- the FDA or foreign regulatory authorities may request additional clinical trials, including an additional Phase 3 trial, relating to our NDA submissions;
- the FDA or a foreign regulatory authority may change its approval policies or adopt new regulations that may negatively affect or delay our ability to bring a system to market or require additional clinical trials; and
- a system may not be approved for all the requested indications.

The failure or delay of clinical trials could cause an increase in the cost of product development, delay filing of an application for marketing approval or cause we to cease the development of Melphalan/HDS for other indications. If we are unable to develop Melphalan/HDS for other indications, the future growth of our business could be negatively impacted. In addition, we have limited clinical data relating to the effectiveness of Melphalan/HDS in certain types of cancer. Such limited data could slow the adoption of CHEMOSAT and Melphalan/HDS and significantly reduce our ability to commercialize CHEMOSAT and Melphalan/HDS.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

FDA has granted us six orphan drug designations and we may seek additional orphan drug designations in the future.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same indication for that drug during that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We cannot assure you that any future application for orphan drug designation with respect to any product candidate will be granted. If we are unable to obtain orphan drug designation in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even if

we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

We rely on third parties to conduct certain elements of the clinical trials for CHEMOSAT and Melphalan/HDS, and if they do not perform their obligations to us, we may not be able to obtain regulatory approvals for our system.

We design the clinical trials for Melphalan/HDS, but rely on academic institutions, corporate partners, contract research organizations and other third parties to assist in managing, monitoring and otherwise carrying out these trials. We rely heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on its own. We rely on third parties to conduct monitoring and data collection of our ongoing and future clinical trials, including our Phase 3 ocular melanoma trial and pivotal ICC trial. Although we rely on these third parties to manage the data from these clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with our general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. Our reliance on third parties does not relieve us of these responsibilities and requirements and if we or the third parties upon whom we rely for our clinical trials fail to comply with the applicable GCPs, the data generated in our clinical trials may be deemed unreliable and the FDA or other foreign regulatory agencies may require us to perform additional trials before approving our marketing application. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCPs. In addition, our clinical trials must be conducted with product that complies with the FDA's cGMP requirements. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, and may result in a failure to obtain regulatory approval for Melphalan/HDS if these requirements are not met.

Purchasers of CHEMOSAT in the EU may not receive third-party reimbursement or such reimbursement may be inadequate. Without adequate reimbursement, commercialization of CHEMOSAT in the EU may not be successful.

We have obtained the right to affix the CE Mark for CHEMOSAT, and under the definitive licensing agreement, or the medac License, for CHEMOSAT commercialization in Europe with medac, medac intends to seek third-party or government reimbursement within those countries in the EU where it expects to market and sell CHEMOSAT. In Germany, we had received a ZE diagnostic-related group code, or ZE Code, which, beginning in 2016, permits hospitals in Germany to obtain reimbursement for CHEMOSAT procedures. Negotiations on the amount of reimbursement to be received under the ZE Code were concluded in 2016 and the procedure was reimbursed under the ZE Code in 2017. Reimbursement negotiations under the ZE system are conducted annually. Consequently, reimbursement obtained may not be for the full amount sought. In countries where medac is able to obtain reimbursement, local policy could limit our ability to obtain adequate and consistent reimbursement and limit other sales opportunities in those countries.

In other countries, until medac obtains government reimbursement, it will rely on private payors or local pre-approved funds where available. There are also no assurances that third-party payors or government health agencies of Member States of the EU will reimburse use of CHEMOSAT in the long term or at all. Further, each country has its own protocols regarding reimbursement, so successfully obtaining third party or government health agency reimbursement in one country does not necessarily translate to similar reimbursement in other EU countries. Physicians, hospitals and other health care providers may be reluctant to purchase CHEMOSAT if they do not receive substantial reimbursement for the cost of using the product from third-party payors or government entities. The lack of adequate reimbursement may significantly limit sales opportunities in the EU.

The success of our products may be harmed if the government, private health insurers or other third-party payers do not provide sufficient coverage or reimbursement.

Our ability to commercialize CHEMOSAT under the medac License and Melphalan/HDS successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. Melphalan/HDS is currently not approved by the FDA. Medicare, Medicaid, private health insurance plans and their foreign equivalents will not reimburse the use of Melphalan/HDS since the product is currently not approved outside the EU. We will seek reimbursement by third-party payors of the cost of Melphalan/HDS after its use is approved, but there are no assurances that adequate third-party coverage will be available to establish and maintain price levels sufficient for us to realize an appropriate return on our investment in developing new therapies. Government, private health insurers and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing. Accordingly, even if coverage and reimbursement are

provided by government, private health insurers and third-party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for healthcare providers.

Implementation of healthcare reforms in the United States and in significant overseas markets may limit the ability to commercialize CHEMOSAT and Melphalan/HDS and the demand for CHEMOSAT and Melphalan/HDS. Healthcare providers may respond to such cost-containment pressures by choosing lower cost products or other therapies. In March 2010, the Patient Protection and Affordable Care Act and Health Care and Education Reconciliation Act of 2010, or the ACA, was enacted in the United States, which included a number of provisions aimed at improving quality and decreasing costs. The Trump administration has taken executive actions and has eliminated the individual shared responsibility penalty portion of ACA. A court decision finding that the ACA is unconstitutional is on appeal.

CHEMOSAT and Melphalan/HDS may not achieve sufficient acceptance by the medical community to sustain our business.

The commercial success of CHEMOSAT and Melphalan/HDS, if approved, will depend upon their acceptance by the medical community and third-party payers as clinically useful, cost effective and safe. Acceptance by the medical community may depend on the extent to which leaders in the scientific and medical communities publish scientific papers in reputable academic journals. If testing and clinical practice do not confirm the safety and efficacy of CHEMOSAT and Melphalan/HDS or even if further testing and clinical practice produce positive results but the medical community does not view these favorably, and CHEMOSAT and Melphalan/HDS as effective and desirable, our efforts to market CHEMOSAT and Melphalan/HDS may fail, which would cause us to cease operation.

We may be subject, directly or indirectly, to federal and state health care fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our drug candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may affect, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal health care program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010 requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- state law and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including exclusion from payment by federal health care programs, civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Compliance with laws and regulations pertaining to the privacy and security of health information may be time consuming, difficult and costly, particularly in light of increased focus on privacy issues in countries around the world, including the U.S. and the EU.

We are subject to various domestic and international privacy and security regulations. The confidentiality, collection, use and disclosure of personal data, including clinical trial patient-specific information, are subject to governmental regulation generally in the country that the personal data were collected or used. In the United States we are subject to various state and federal privacy and data security regulations, including but not limited to HIPAA and as amended in 2014 by the HITECH Act. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In the EU personal data includes any information that relates to an identified or identifiable natural person with health information carrying additional obligations, including obtaining the explicit consent from the individual for collection, use or disclosure of the information. In addition, we are subject to EU regulation with respect to protection of and cross-border transfers of such data out of the EU, and this regulation will become more stringent in May 2018 when the EU's General Data Protection Regulation (GDPR) comes into effect. Furthermore, the legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues. The United States and the EU and its member states continue to issue new privacy and data protection rules and regulations that relate to personal data and health information.

Compliance with these laws may be time consuming, difficult and costly. If we fail to comply with applicable laws, regulations or duties relating to the use, privacy or security of personal data we could be subject to the imposition of significant civil and criminal penalties, be forced to alter our business practices and suffer reputational harm.

Changes in health care law and implementing regulations, including government restrictions on pricing and reimbursement, as well as health care policy and other health care payor cost-containment initiatives, may have a material adverse effect on us.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system and efforts to control health care costs, including drug prices, that could have a significant negative impact on our business, including preventing, limiting or delay regulatory approval of our drug candidates and reducing the sales and profits derived from our products once they are approved.

For example, in the United States, the Patient Protection and Affordable Care Act of 2010, or ACA, substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Many provisions of ACA impact the biopharmaceutical industry, including that in order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS. Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of ACA. There is continued uncertainty about the implementation of ACA, including the potential for further amendments to the ACA and legal challenges to or efforts to repeal the ACA.

We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be.

The "Novel Coronavirus Disease 2019" ("COVID-19") pandemic has materially and adversely affected our clinical trial operations and may materially and adversely affect our financial results.

The COVID-19 pandemic has affected many countries, including the United States and several European countries, where we are currently conducting our FOCUS Trial and ALIGN Trial. In response to the pandemic, hospitals participating in the trials in affected countries have taken a number of actions, including restricting elective and other procedures that are not deemed to be life-threatening, suspending clinical trial activities and limiting access to data monitoring. As a result, patients enrolled in our clinical trials have had the start of their treatments postponed and ongoing treatment regimens may be delayed. In addition, we do not have sufficient access to monitor trial data on a timely basis. These restrictions have had a materially adverse impact on our clinical operations. For example, as noted under "Business - Clinical Development Program - The FOCUS Trial," the completion of our FOCUS Trial and the release of the top-line data will be delayed beyond our prior expectations. The extent to which the COVID-19 pandemic may impact our clinical trial operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the spread and severity of COVID-19, and the effectiveness of governmental actions in response to the pandemic. Furthermore, the spread of COVID-19 may materially impact our ability to recruit and retain patients.

We expect that actions taken in response to the COVID-19 pandemic will also negatively impact sales of CHEMOSAT. As noted above, some hospitals are restricting procedures that are not deemed to be life-threatening at this time. Because CHEMOSAT is not deemed to be a life-threatening procedure, we expect that the number of procedures performed will decline. While we do not expect revenues from CHEMOSAT procedures to be material to us, a decrease in the number of procedures performed will adversely affect our expected revenues and our financial results.

These consequences of the COVID-19 pandemic will delay and could adversely affect our ability to obtain regulatory approval for and to commercialize our products, increase our operating expenses, and could have a material adverse effect on our financial results.

Consolidation in the healthcare industry could lead to demands for price concessions.

The cost of healthcare has risen significantly over the past decade and numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the medical device industry. Group purchasing organizations, independent delivery networks and large single accounts in the United States and foreign markets may result in a consolidation of purchasing decisions for potential healthcare provider customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances which may exert further downward pressure on the price of CHEMOSAT and Melphalan/HDS and adversely impact our business, financial condition and results of operations.

Further, third-party payors may deny reimbursement if they determine that CHEMOSAT and/or Melphalan/HDS is not used in accordance with established payor protocols regarding cost effective treatment methods or is used outside its approved indication or for forms of cancer or with drugs not specifically approved by the FDA or other foreign regulatory bodies in the future. Without reimbursement, physicians, hospitals and other health care providers will be less likely to purchase CHEMOSAT and/or Melphalan/HDS, thereby harming our results of operations.

Risks Related to Manufacturing, Commercialization and Market Acceptance of CHEMOSAT and Melphalan/HDS

There are three third-party manufacturers of melphalan in certain countries of the EU of which we are aware. If any of these manufacturers fails to provide end-users with adequate supplies of melphalan or fails to comply with the requirements of regulatory authorities, we may be unable to successfully commercialize our product in the EU.

Under the current regulatory scheme in the EU, CHEMOSAT is approved for marketing as a device only, and doctors will separately obtain melphalan for use with CHEMOSAT. Although melphalan has been approved in the EU for over a decade, we are aware that there are currently three approved manufacturers of melphalan in certain countries of the EU. As a result, there may not be sufficient supply of melphalan for use with CHEMOSAT, and any adverse change in a manufacturer's commercial operations or regulatory approval status may seriously impair our sales opportunities in the EU. Additionally, melphalan is not available in certain foreign countries outside the EU where we may seek to market CHEMOSAT. If supply of melphalan remains limited or unavailable, we will be unable to commercialize CHEMOSAT in these markets, thereby limiting future sales opportunities.

If we cannot maintain or enter into acceptable arrangements for the production of melphalan and other chemotherapeutic agents we will be unable to successfully commercialize Melphalan/HDS in the United States or complete our global Phase 3 trial in ocular melanoma liver metastases, registration trial in ICC, or any future clinical trials.

We have entered into a manufacturing and supply agreements with several suppliers for our supply of melphalan for injection for our clinical trials. We may pursue agreements with additional contract manufacturers to produce melphalan and other chemotherapeutic agents for use in the future for our clinical trial program and the commercialization of CHEMOSAT and Melphalan/HDS, as well as for labeling and finishing services. We may not be able to enter into such arrangements on acceptable terms or at all. Every manufacturer is subject to inspection by FDA and must meet all cGMP regulatory requirements. To manufacture melphalan or other chemotherapeutic agents on our own, we would have to develop a manufacturing facility that complies with FDA requirements and regulations for the production of melphalan and each other chemotherapeutic agent we choose to manufacture for use with our system. Developing these resources would be an expensive and lengthy process and would have a material adverse effect on our revenues and profitability. If we are unable to obtain sufficient melphalan and labeling services on acceptable terms, if it should encounter delays or difficulties in our relationships with current and future suppliers or if current and future suppliers of melphalan do not comply with applicable regulations for the manufacturing and production of melphalan, our business, financial condition and results of operations may be materially harmed.

If we cannot successfully manufacture CHEMOSAT and Melphalan/HDS, our ability to develop and commercialize the system would be impaired.

We manufacture certain components of our products, including our proprietary filter media, and assemble and package CHEMOSAT and Melphalan/HDS at our facility in Queensbury, New York. We have established our European headquarters and packaging/labeling/distribution facility in Galway, Ireland where we intend to conduct final manufacturing and assembly in the future. We currently utilizes third-parties to manufacture some components of CHEMOSAT and Melphalan/HDS.

We have a limited manufacturing history and we may not be able to manufacture our products in sufficient commercial quantities, in a cost-effective manner or in compliance with the regulatory requirements applicable to such manufacturing. Additionally, we may have difficulty obtaining components for our products from our third-party suppliers in a timely manner or at all which may adversely affect our ability to deliver CHEMOSAT and Melphalan/HDS to purchasers.

In addition to limiting sales opportunities, delays in manufacturing CHEMOSAT and Melphalan/HDS may adversely affect our ability to obtain regulatory approval in the United States and other jurisdictions. Our ability to conduct timely clinical trials in the United States and abroad depends on our ability to manufacture the system, including sourcing the chemotherapeutic agents or other compounds through third parties in accordance with FDA and other regulatory requirements. If we are unable to manufacture CHEMOSAT and Melphalan/HDS in a timely manner, we may not be able to conduct the clinical trials required to obtain regulatory approval and commercialize our product.

We have implemented quality systems throughout our organization designed to enable us to satisfy the various international quality system regulations including those of the FDA with respect to products sold in the United States and those established by the International Standards Organization, or ISO, with respect to products sold in the EU. We are required to maintain ISO 13485 certification for medical devices to be sold in the EU, which requires, among other items, an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. All of our facilities are presently ISO 13485:2016 certified. If our Queensbury, NY fails to maintain compliance with ISO 13485 and FDA cGMP or fails to pass facility inspection or audits, our ability to manufacture at the facility could be limited or terminated. In the future, we may manufacture and assemble CHEMOSAT and Melphalan/HDS in our Galway, Ireland facility or elsewhere in the EU, and any facilities in the EU would have to obtain and maintain similar approvals or certifications of compliance.

We do not have written contracts with all of our suppliers for the manufacture of components for CHEMOSAT and Melphalan/HDS.

We do not have written contracts with all suppliers for the manufacture of components for CHEMOSAT and Melphalan/HDS. If we are unable to obtain an adequate supply of the necessary components or negotiate acceptable terms, we may not be able to manufacture CHEMOSAT and Melphalan/HDS in commercial quantities or in a cost-effective manner, and commercialization of CHEMOSAT and Melphalan/HDS in the United States, the EU and elsewhere may be delayed. In addition, certain components are available from only a limited number of sources. Components of CHEMOSAT and Melphalan/HDS are currently manufactured for us in small quantities and may require significantly greater quantities to further commercialize the product. We may not be able to find alternate sources of comparable components. If we are unable to obtain adequate supplies of components from existing suppliers or need to switch to an alternate supplier and obtain FDA or other regulatory agency approval of that supplier, commercialization of CHEMOSAT and Melphalan/HDS may be delayed.

Even if we receive FDA or other foreign regulatory approvals, we may be unsuccessful in commercializing CHEMOSAT and Melphalan/HDS in markets outside the EU, because of inadequate infrastructure or an ineffective commercialization strategy.

Outside the EU, even if we obtain regulatory approval from the FDA or other foreign regulatory agencies, our ability to commercialize CHEMOSAT and Melphalan/HDS may be limited due to our inexperience in developing a sales, marketing and distribution infrastructure. If we are unable to develop this infrastructure in the United States or elsewhere or to collaborate with an alliance partner to market our products in the United States or foreign countries, particularly in Asia, our efforts to commercialize CHEMOSAT and Melphalan/HDS or any other product outside of the EU may be less successful.

Even if we are successful in commercializing CHEMOSAT and Melphalan/HDS in the EU, we may not be successful in the United States and other foreign countries. Each country requires a different commercialization strategy, so our EU marketing strategy may not translate to other markets. Without a successful commercialization strategy tailored for each market, our efforts to promote and market CHEMOSAT in each of our target markets may fail in any or all of those markets.

Our plan to use collaborative arrangements with third parties to help finance and to market and sell CHEMOSAT and Melphalan/HDS may not be successful.

We may be unable to enter into collaborative agreements without additional clinical data or unable to continue a collaborative agreement as a result of unsuccessful future clinical trials. Additionally, we may face competition in its search for alliances. As a result, we may not be able to enter into any additional alliances on acceptable terms, if at all. Our collaborative relationships may never result in the successful development or commercialization of CHEMOSAT and Melphalan/HDS or any other product. The success of any collaboration will depend upon our ability to perform our obligations under any agreements as well as factors beyond our control, such as the commitment of our collaborators and the timely performance of their obligations. The terms of any such collaboration may permit our collaborators to abandon the alliance at any time for any reason or prevent us from terminating arrangements with collaborators who do not perform in accordance with our expectations or our collaborators may breach their agreements with us. In addition, any third parties with which we collaborate may have significant control over important aspects of the development and commercialization of our products, including research and development, market identification, marketing methods, pricing, composition of sales force and promotional activities. We will not control the amount and timing of resources that any collaborator may devote to our research and development programs or the commercialization, marketing or distribution of our products. We may not be able to prevent any collaborators from pursuing alternative technologies or products that could result in the development of products that compete with CHEMOSAT and Melphalan/HDS or the withdrawal of their support for our products. The failure of any such collaboration could have a material adverse effect on our business.

If we fail to overcome the challenges inherent in international operations, our business and results of operations may be materially adversely affected.

Currently we have only received authorization to market CHEMOSAT in the EU, and intend to seek similar authorization or approvals in other foreign countries. As a result, we expect international sales of CHEMOSAT to account for a significant portion of our revenue, which exposes us to risks inherent in international operations. To accommodate our international sales, we will need to further invest financial and management resources to develop an international infrastructure that will meet the needs of our customers. Accordingly, we will face additional risks resulting from our international operations including:

- difficulties in enforcing agreements and collecting receivables in a timely manner through the legal systems of many countries outside the United States;
- the failure to satisfy foreign regulatory requirements to market its products on a timely basis or at all;
- availability of, and changes in, reimbursement within prevailing foreign healthcare payment systems;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign sales or marketing employees and agents;
- limited protection for intellectual property rights in some countries;
- fluctuations in currency exchange rates;
- the possibility that foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade;
- the possibility of any material shipping delays;
- significant changes in the political, regulatory, safety or economic conditions in a country or region;
- protectionist laws and business practices that favor local competitors; and
- trade restrictions, including the imposition of, or significant changes to, the level of tariffs, customs duties and export quotas.

If we fail to overcome the challenges it encounters in our international operations, our business and results of operations may be materially adversely affected.

Rapid technological developments in treatment methods for liver cancer and competition with other forms of liver cancer treatments could affect our ability to achieve meaningful revenues or profit.

Competition in the cancer treatment industry is intense. CHEMOSAT and Melphalan/HDS compete with all forms of liver cancer treatments that are alternatives to surgical resection. Many of our competitors have substantially greater resources and considerable experience in conducting clinical trials and obtaining regulatory approvals. If these competitors develop more effective or more affordable products or treatment methods, or achieve earlier product development, our revenues or profitability will be substantially reduced.

If another company has orphan drug designations for the same drug and indication as us and receives marketing approval before we do, then we will be blocked from marketing approval for seven years from the date of its approval for the same indication of use unless we can make a showing of the clinical superiority of our drug.

The loss of key personnel could adversely affect our business.

Our success depends upon the efforts of our employees. The loss of any of our senior executives or other key employees could harm its business. Competition for experienced personnel is intense and, if key individuals leave us, we could be adversely affected if suitable replacement personnel are not quickly identified and hired. Competition for qualified individuals exists in all functional areas, which makes it difficult to attract and retain the qualified employees we need to operate our business. Our success also depends in part on our ability to attract and retain highly qualified scientific, technical, commercial and administrative personnel. If we are unable to attract new employees and retain our current key employees, our ability to compete could be adversely affected and the development and commercialization of our products could be delayed or negatively impacted.

We rely on the proper function, availability and security of information technology systems to operate our business and a cyber-attack or other breach of these systems could have a material adverse effect on our business, financial condition or results of operations.

We rely on information technology systems to process, transmit, and store electronic information in our day-to-day operations. Similar to other companies, the size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards. Any failure by us to maintain or protect our information technology systems and data integrity, including from cyber-attacks, intrusions or other breaches, could result in the unauthorized access to personally identifiable information, theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Any of these event may cause us to have difficulty preventing, detecting, and controlling fraud, be subject to legal claims and liability, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach or theft of intellectual property, or suffer other adverse consequences, any of which could have a material adverse effect on our business, financial condition or results of operations.

Any current or future outbreak of a health epidemic or other adverse public health developments, such as the current outbreak of the COVID-19, could disrupt our manufacturing and supply chain, and adversely affect our business and operating results.

Our business could be adversely affected by the effects of health epidemics, specifically COVID-19. For example, our materials suppliers could be disrupted by conditions related to COVID-19, or other epidemics, possibly resulting in disruption to our supply chain. If our suppliers are unable or fail to fulfill their obligations to us for any reason, we may not be able to manufacture our products and satisfy customer demand or our obligations under sales agreements in a timely manner, and our business could be harmed as a result. At this point in time, there is uncertainty relating to the potential effect of COVID-19 on our business. Infections may become more widespread and should that limit our ability to manufacture our products or cause supply disruptions it would have a negative impact on our business, financial condition and operating results. In addition, a significant health epidemic could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect the market for our products, which could have a material adverse effect on our business, operating results and financial condition.

Risks Related to Intellectual Property

Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.

Our success depends significantly on our ability to maintain and protect our proprietary rights in the technologies and inventions used in or embodied by our product. To protect our proprietary technology, we rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, as well as nondisclosure, confidentiality, license and other contractual restrictions in our manufacturing, consulting, employment and other third party agreements. These legal means may afford only limited protection, however, and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

We have not and may not be able to adequately protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product and technologies in any or all countries throughout the world could be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the

breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from copying our inventions in foreign countries, to the extent we can in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection that covers the commercial products to develop their own competing products that are the same or substantially the same as our commercial product and, further, may export otherwise infringing products to territories where we have patent protection, but judicial systems do not adequately enforce patents to cause infringing activities to be ceased.

We do not have patent rights in certain foreign countries in which a market for our product and technologies exists or may exist in the future. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our product and technologies.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Moreover, the United States Patent and Trademark Office, or the USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our product and technologies.

Our success depends in part on our ability to obtain patents, which can be an expensive, time consuming, and uncertain process, and the value of the patents is dependent in part on the breadth of coverage and the relationship between the coverage and the commercial product.

The patent position of medical drug and device companies is generally highly uncertain. The degree of patent protection we require may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us sufficient exclusivity, or to gain or keep our competitive advantage. For example:

- we might not have been the first to invent or the first to file patent applications on the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or license from others in the future may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- any patents we obtain or license from others in the future may not be valid or enforceable; and
- we may not develop additional proprietary technologies that are patentable The process of applying for patent protection itself is time consuming and expensive and we cannot assure you that we have prepared or will be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is possible that innovation over the course of development and commercialization may lead to changes in CHEMOSAT and Melphalan/HDS methods and/or devices that cause such methods and/or devices to fall outside the scope of the patent protection we have obtained and the patent protection we have obtained may become less valuable. It is also possible that we will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. In addition, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. Moreover, we cannot assure you that all of our pending patent applications will issue as patents or that, if issued, they will issue in a form that will be advantageous to us.

Our success depends in part on our ability to commercialize CHEMOSAT and Melphalan/HDS prior to the expiration of our patent protection.

Due to the uncertainty of the patent prosecution process, there are no guarantees that any of our pending patent applications will result in the issuance of a patent. Even if we are successful in obtaining a patent, patents have a limited lifespan. In the United States, the natural expiration of a utility patent typically is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our CHEMOSAT and Melphalan/HDS methods and devices, we may be open to competition from generic versions of such methods and devices.

We may in the future become involved in lawsuits to protect or enforce our intellectual property, or to defend our products against assertion of intellectual property rights by a third party, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To stop any such infringement or unauthorized use, litigation may be necessary. Our intellectual property has not been tested in litigation. There is no assurance that any of our issued patents will be upheld if later challenged or will provide significant protection or commercial advantage. A court may declare our patents invalid or unenforceable, may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question, or may interpret the claims of our patents narrowly, thereby substantially narrowing the scope of patent protection they afford. Because of the length of time and expense associated with bringing new medical drugs and devices to the market, the healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. Other parties may challenge patents, patent claims or patent applications licensed or issued to us or may design around technologies we have patented, licensed or developed.

In addition, third parties may initiate legal or administrative proceedings against us to challenge the validity or scope of our intellectual property rights, such as inter partes review, post-grant review, re-examination or opposition proceedings, before the USPTO, the European Patent Office or other foreign counterparts. Third parties may also allege an ownership right in our patents, as a result of their past employment or consultancy with us. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our product in one or more foreign countries.

The medical device industry has been characterized by frequent and extensive intellectual property litigation. Our competitors or other patent holders may assert that our products and the methods employed in our products are covered by their patents. Although we have performed a search for third-party patents and believe we have adequate defenses available if faced with any allegations that we infringe these third-party patents, it is possible that CHEMOSAT and Melphalan/HDS could be found to infringe these patents. It is also possible that our competitors or potential competitors may have patents, or have applied for, will apply for, or will obtain patents that will prevent, limit or interfere with our ability to make, have made, use, sell, import or export our product. If our products or methods are found to infringe, we could be prevented from manufacturing or marketing our product.

Companies in the medical drug/device industry may use intellectual property infringement litigation to gain a competitive advantage. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, avoiding patent infringement may be difficult. Litigation may be necessary to enforce any patents issued or assigned to us or to determine the scope and validity of third-party proprietary rights. Litigation could be costly and could divert our attention from our business. There are no guarantees that we will receive a favorable outcome in any such litigation. If a third party claims that we infringed its patents, any of the following may occur:

- we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a competitor's patent;
- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and
- we may have to redesign our product so that it does not infringe upon others' patent rights, which may not be possible or could require substantial funds or time.

Litigation related to infringement and other intellectual property claims such as trade secrets, with or without merit, is unpredictable, can be expensive and time-consuming, and can divert management's attention from our core business. If we lose this kind of litigation, a court could require us to pay substantial damages, treble damages, and attorneys' fees, and could prohibit us from using technologies essential to our product, any of which would have a material adverse effect on our business, results of operations, and financial condition. If relevant patents are upheld as valid and enforceable and we are found to infringe, we could be prevented from selling our product unless we can obtain licenses to use technology or ideas covered by such patents. We do not know whether any

necessary licenses would be available to us on satisfactory terms, if at all. If we cannot obtain these licenses, we could be forced to design around those patents at additional cost or abandon the product altogether. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could cause the price of our common stock to decline.

If others have filed patent applications with respect to inventions for which we already have patents issued to us or have patent applications pending, we may be forced to participate in interference or derivation proceedings declared by the USPTO to determine priority of invention, which could also be costly and could divert our attention from our business. If the USPTO declares an interference and determines that our patent or application is not entitled to a priority date earlier than that of the other patent application, our ability to maintain or obtain those patent rights will be curtailed. Similarly, if the USPTO declares a derivation proceeding and determines that the invention covered by our patent application was derived from another, we will not be able to obtain patent coverage of that invention.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before CHEMOSAT and Melphalan/HDS or any other product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Not all of our United States patent rights have corresponding patent rights effective in Europe or other foreign jurisdictions. Similar considerations apply in any other country where we are prosecuting patent applications, have been issued patents, or have decided not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product and our technologies.

Legislation introduced earlier this decade increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the United States patent system from a “first-to-invent” system to a “first-inventor-to-file” system. Under a “first-inventor-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-inventor-to-file provisions, only became effective on March 16, 2013. As case law continues to develop in response to this legislation, it is not yet clear what the full impact of the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications. Furthermore, the United States Supreme Court and the United States Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain and enforce or defend additional patent protection in the future.

Our trademarks may be infringed or successfully challenged, resulting in harm to our business.

We rely on our trademarks as one means to distinguish our product from the products of our competitors, and we have registered or applied to register many of these trademarks. The USPTO or foreign trademark offices may deny our trademark applications, however, and even if published or registered, these trademarks may be ineffective in protecting our brand and goodwill and may be successfully opposed or challenged. Third parties may oppose our trademark applications, or otherwise challenge our use of our trademarks. In addition, third parties may use marks that are confusingly similar to our own, which could result in confusion among our customers, thereby weakening the strength of our brand or allowing such third parties to capitalize on our goodwill. In such an event, or if our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademark rights in the face of any such infringement.

We may rely primarily on trade secret protection for important proprietary technologies in the European Union.

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Specifically in the EU, we rely on design patent and trade secret protection for CHEMOSAT and Melphalan/HDS. Without utility patent protection in the EU covering the current version of CHEMOSAT and Melphalan/HDS, CHEMOSAT and Melphalan/HDS will only be covered by design patent and trade secret protection. Unlike patents, trade secrets are only recognized under applicable law if they are kept secret by restricting their disclosure to third parties. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. However, certain consultants and third parties with whom we have business relationships, and to whom in some cases we have disclosed trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device industry, including companies, universities and research organizations that are developing competing products. In addition, some of our former employees who were exposed to certain of our trade secrets and other proprietary knowledge in the course of their employment may seek employment with, and become employed by, our competitors. We cannot be assured that consultants, employees and other third parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Trade secret protection does not prevent independent discovery of the technology or proprietary information or use of the same. Competitors may independently duplicate or exceed our technology in whole or in part. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If we are not successful in maintaining the confidentiality of our technology, the loss of trade secret protection or know-how relating to CHEMOSAT and Melphalan/HDS will significantly impair our ability to commercialize CHEMOSAT in the EU, and our value and results of operations will be harmed. In particular, we rely on trade secret protection for the filter media, which is a key component of our system.

Similar considerations apply in other foreign countries where we receive approval as mentioned in the section "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Intellectual Property and Other Rights*". Since we do not have issued patents for the current version of CHEMOSAT and Melphalan/HDS in these countries, our ability to successfully commercialize CHEMOSAT and Melphalan/HDS will depend on our ability to maintain trade secret protection in these markets.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers, competitors, or other third parties. Although we endeavor to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our product, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers or other third parties. An inability to incorporate technologies or features that are important or essential to our product may prevent us from selling our product. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product.

Risks Related to Products Liability

We may be the subject of product liability claims or product recalls, and we may be unable to maintain insurance adequate to cover potential liabilities.

Our business exposes us to potential liability risks that may arise from clinical trials and the testing, manufacture, marketing, sale and use of CHEMOSAT and Melphalan/HDS. In addition, because CHEMOSAT and Melphalan/HDS are intended for use in patients with cancer, there is an increased risk of death among the patients treated with our system which may increase the risk of product liability lawsuits related to clinical trials or commercial sales. We may be subject to claims against us even if the injury is due to the actions of others. For example, if the medical personnel that use our system on patients are not properly trained or are negligent in the

use of the system, the patient may be injured, which may subject us to claims. Were such a claim asserted, we would likely incur substantial legal and related expenses even if we prevail on the merits. Claims for damages, whether or not successful, could cause delays in clinical trials and result in the loss of physician endorsement, adverse publicity and/or limit our ability to market and sell the system, resulting in loss of revenue. In addition, it may be necessary for us to recall products that do not meet approved specifications, which would also result in adverse publicity, as well as resulting in costs connected to the recall and loss of revenue. A successful products liability claim or product recall would have a material adverse effect on our business, financial condition and results of operations. While we currently carry product liability and clinical trial insurance coverage, it may be insufficient to cover one or more large claims.

Risks Related to Our Common Stock

The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors.

The trading price of our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or its competitors, its ability or inability to raise the additional capital needed and the terms on which it may be raised, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading, regardless of our financial condition, results of operations, business or prospects. Among the factors that may cause the market price of its common stock to fluctuate are the risks described in this “Risk Factors” section and other factors, including:

- fluctuations in quarterly operating results or the operating results of competitors;
- variance in financial performance from the expectations of investors;
- changes in the estimation of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect financial results;
- failure of our products to achieve or maintain market acceptance or commercial success;
- conditions and trends in the markets served;
- changes in general economic, industry and market conditions;
- success of competitive products and services;
- changes in market valuations or earnings of competitors;
- changes in pricing policies or the pricing policies of competitors;
- announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;
- potentially negative announcements, such as a review of any of our filings by the SEC, changes in accounting treatment or restatements of previously reported financial results or delays in our filings with the SEC:
- changes in legislation or regulatory policies, practices or actions;
- the commencement or outcome of litigation involving us, our general industry or both;
- our filing for protection under federal bankruptcy laws;
- recruitment or departure of key personnel;
- changes in capital structure, such as future issuances of securities or the incurrence of additional debt;
- actual or expected sales of common stock by stockholders; and
- the trading volume of our common stock.

In addition, the stock markets, in general, the OTC and the market for pharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of its business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose it to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management’s attention and resources, which could further materially harm our financial condition and results of operations.

Under certain circumstances, we may become obligated to pay liquidated damages or to issue additional shares of common stock under the terms of certain of our outstanding securities.

We are liable to Rosalind for liquidated damages under the terms of the registration rights agreements relating to the Private Placements and the Debt Exchange for the period from December 28, 2019 and January 7, 2020. Furthermore, if we issue new shares at a price less than $23.04 per share, under the terms of the Preferred Stock and the 2019 Warrants, the Conversion Price of the Series E and Series E-1 Preferred Stock and the Exercise Price of the 2019 Warrants will be reduced to the offering price per share upon the consummation of a new offering which will require us to issue additional shares of common stock upon the conversion of the Preferred Stock. We will also be liable for liquidated damages if we fail to comply with certain covenants contained in the registration rights agreements relating to the Private Placements and the Debt Exchange.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock and could impair our ability to raise additional equity capital.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could cause the market price of our common stock to decline and could impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future sales of our shares of common stock or other equity-related securities would have on the market price of our common stock.

We have a history of reverse splits, which have severely impacted our common stock price.

Since our initial public offering in 2000, we have effected five reverse stock splits, for a cumulative ratio since our IPO of 1:31,360,000,000. Each such reverse split has resulted in an effective decline in the price of our common stock. There can be no assurance that we will not be required to effect one or more additional reverse stock splits which could further impact the market price and liquidity of our common stock.

Anti-takeover provisions in our Amended and Restated Certificate of Incorporation and By-laws may reduce the likelihood of a potential change of control, or make it more difficult for our stockholders to replace management.

Certain provisions of our Amended and Restated Certificate of Incorporation and By-laws could have the effect of making it more difficult for our stockholders to replace management at a time when a substantial number of stockholders might favor a change in management. These provisions include:

- providing for a staggered board; and
- authorizing the board of directors to fill vacant directorships or increase the size of its board of directors.

Furthermore, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval. Any series of preferred stock is likely to be senior to the common stock with respect to dividends, liquidation rights and, possibly, voting rights. The board's ability to issue preferred stock may have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock.

We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future.

We intend to retain all earnings for use in connection with the expansion of our business and for general corporate purposes. The board of directors will have the sole discretion in determining whether to declare and pay dividends in the future. The declaration of dividends will depend on profitability, financial condition, cash requirements, future prospects and other factors deemed relevant by our board of directors. Our ability to pay cash dividends in the future could be limited or prohibited by the terms of financing agreements that we may enter into or by the terms of any preferred stock that may be authorized and issued. We do not expect to pay dividends in the foreseeable future. As a result, holders of our common stock must rely on stock appreciation for any return on their investment.

If we engage in acquisitions, reorganizations or business combinations, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time, we may consider strategic alternatives, such as acquiring businesses, technologies or products or entering into a business combination with another company. If we do pursue such a strategy, we could, among other things:

- issue equity securities that would dilute current stockholders' percentage ownership;

- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources in integrating new businesses, personnel, intellectual property, technologies and products;
- assume substantial actual or contingent liabilities;
- reprioritize our programs and even cease development and commercialization of CHEMOSAT and Melphalan/HDS;
- suffer the loss of key personnel, or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company or a combination of both on terms that certain of our stockholders may not deem desirable.

Although we intend to evaluate and consider different strategic alternatives, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our corporate offices currently occupy 6,877 square feet of office space at 1633 Broadway, Suite 22C, New York, New York under a sub-lease agreement that expires in February 2021. We lease one additional space in the United States comprised of approximately 6,000 square feet at 95-97 Park Road in Queensbury, New York. The lease agreement expires in November 2020. See Note 13 to our audited consolidated financial statements contained in this Annual Report on Form 10-K for more details. We also own a building comprised of approximately 10,320 square feet at 566 Queensbury Avenue in Queensbury, New York. These facilities house manufacturing, quality assurance and quality control, research and development, and office space functions. We also own approximately four acres of land at 12 and 14 Park Road in Queensbury, New York. In addition, we lease a facility for office and manufacturing comprised of approximately 19,200 square feet at 19 Mervue, Industrial Park in Galway, Ireland under a lease agreement that expires in August 2021. We have sublet a portion of this facility to an unaffiliated third-party. We believe substantially all of our property and equipment is in good condition and that we have sufficient capacity to meet current operational needs.

Item 3. Legal Proceedings.

From time to time, claims are made against the Company in the ordinary course of business, which could result in litigation. Claims and associated litigation are subject to inherent uncertainties and unfavorable outcomes could occur, such as monetary damages, fines, penalties or injunctions prohibiting us from selling our products or engaging in other activities.

The occurrence of an unfavorable outcome in any specific period could have a material adverse effect on our results of operations for that period or future periods.

Item 4. Mine Safety Disclosures.

Not applicable.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is traded on the OTC Markets LLC under the symbol "DCTH".

On March 25, 2020 there were approximately 54 stockholders of record of our common stock.

Our website is www.delcath.com. We make available free of charge on or through our website our 10-K, 10-Q and 8-K reports, including exhibits, as soon as reasonably practicable after being filed with or furnished to the SEC.

Dividend Policy

We have never declared or paid cash dividends on our common stock and have no intention to do so in the foreseeable future.

Recent Sales of Unregistered Securities

On February 26, 2020, we issued 2,717 shares of restricted common stock in relation to certain advisory services received by us. In connection with the foregoing, we relied upon the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, for transactions not involving a public offering.

Repurchases of Equity Securities

None.

Item 6. Selected Financial Data.

Not required.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Overview

We are an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our lead product candidate, Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System, or Melphalan/HDS, is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, Melphalan/HDS is approved for sale under the trade name Delcath CHEMOSAT ® Hepatic Delivery System for Melphalan, or CHEMOSAT.

Our primary research focus is on ocular melanoma liver metastases, or mOM, and intrahepatic cholangiocarcinoma, or ICC, a type of primary liver cancer, as well as certain other cancers that are metastatic to the liver. We believe that the disease states we are investigating are unmet medical needs that represent significant market opportunities.

We are investigating the objective response rate of Melphalan/HDS in patients with mOM in our FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma, or the FOCUS Trial, a global registration clinical trial. For information on the FOCUS Trial, see "Business—Clinical Development Program—The FOCUS Trial".

We are also conducting the ALIGN Trial, a global Phase 3 clinical trial of Melphalan/HDS in patients with ICC, or the ALIGN Trial. For information on the ALIGN Trial, see "Business—Clinical Development Program—The ALIGN Trial" below.

In addition to the FOCUS Trial and the ALIGN Trial, our commercial development plan also includes a registry for CHEMOSAT cases performed in Europe and sponsorship of select investigator-initiated trials, or IITs.

In the United States, Melphalan/HDS is considered a combination drug and device product and is regulated as a drug by the United States Food and Drug Administration, or the FDA. The FDA has granted us six orphan drug designations, including three orphan designations for the potential use of the drug melphalan for the treatment of patients with mOM, hepatocellular carcinoma and ICC. Melphalan/HDS has not been approved for sale in the United States.

In Europe, our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are commercializing the CHEMOSAT system in select markets in the United Kingdom and the EU, where we believe the prospect of securing reimbursement coverage for the use of CHEMOSAT is strongest.

Our Ability to Continue as a Going Concern

The notes to our consolidated financial statements contained in this Annual Report on Form 10-K for the year ended December 31, 2019 include a disclosure describing the existence of certain conditions that raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any commercialization efforts. Our consolidated financial statements as of December 31, 2019 have been prepared under the assumption that we will continue as a going concern. If we are not able to continue as a going concern, it is likely that holders of our common stock will lose all of their investment. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. See risk factors relating to our financial condition as well as other risk factors that we face in Part 1, Item 1A hereof under the caption "Risk Factors" above.

Our independent registered public accounting firm has issued its report dated March 25, 2020 in connection with the audit of our consolidated financial statements as of December 31, 2019 that includes an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern.

Liquidity and Capital Resources

We received gross proceeds of $29.5 million through two private placements in July and August 2019, providing funding through the second quarter of 2020. We will need to raise additional capital under structures available to us including debt and/or equity offerings. If these sources do not provide the capital necessary to fund our operations, we will need to curtail certain aspects of our operations or consider other means of obtaining additional financing, although there is no guarantee that we could obtain the financing necessary to continue our operations.

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and anticipate that losses will continue over the coming years. There can be no assurance that we will ever generate significant revenues or achieve profitability. We expect to use cash, cash equivalents and investment proceeds to fund our clinical and operating activities. Our future liquidity and capital requirements will depend on numerous factors, including the initiation and progress of clinical trials and research and product development programs; obtaining approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

At December 31, 2019, we had cash, cash equivalents and restricted cash totaling $10.2 million, as compared to cash, cash equivalents and restricted cash totaling $3.6 million at December 31, 2018. During the years ended December 31, 2019 and 2018, the Company used $23.7 million and $14.7 million respectively, of cash in our operating activities.

Our consolidated financial statements as of December 31, 2019 have been prepared under the assumption that we will continue as a going concern for the next twelve months. We expect to incur significant expenses and operating losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern. Because our business does not generate positive cash flow from operating activities, we will need to obtain substantial additional capital in order to fund clinical trial research and support development efforts relating to ocular melanoma liver metastases, ICC, HCC or other indications, and to fully commercialize the product. We believe we will be able to raise additional capital in the event it is in our best interest to do so. We anticipate raising such additional capital by either borrowing money, selling shares of our capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when needed or on acceptable terms, we may be forced to abandon some or all of our development and commercialization efforts, which would have a material adverse effect on the prospects of our business. Further, our assumptions relating to our cash requirements may differ materially from our actual requirements because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the timing, scope, focus and direction of clinical trials and costs related to commercializing the product.

We have funded our operations through a combination of private placements and public offerings of its securities in each of 2000, 2003, 2009, 2010, 2011, 2012, 2013, 2015, 2016, 2018 and 2019, including registered direct offerings in 2007, 2009 and 2013, “at the market” equity offering programs in 2012 and 2013, and by the private placement of convertible notes in 2016 and 2018, and, most recently, in July and August 2019, we raised $29.5 million in the closing of two private placements of convertible preferred stock and warrants to purchase common stock. For a detailed discussion of our various sales of debt and equity securities see Notes 10 and 11 to our audited consolidated financial statements.

In October 2018, we filed a registration statement on Form S-3 with the SEC, which was declared effective on December 21, 2018 and allowed us to offer and sell, from time to time in one or more offerings, up to $100.0 million of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital at a later date. We lost our Form S-3 eligibility due to the late filing of our Annual Report for the year ended December 31, 2018. Absent prior relief from the SEC, we expect to regain S-3 eligibility on June 1, 2020.

Future Capital Needs; Additional Future Funding

Our future results are subject to substantial risks and uncertainties. We have operated at a loss for our entire history and there can be no assurance that we will ever achieve consistent profitability. Based upon the recent financing activities described above, we believe that we have adequate resources to fund operations through June 2020. Additional working capital will be required to continue operations. There can be no assurance that such working capital will be available on acceptable terms, if at all.

Results of Operations for the Year Ended December 31, 2019; Comparisons of Results of the Years Ended December 31, 2019 and 2018

Revenue

We recorded approximately $1.1 million in product revenue and $0.5 million in other revenue during the year ended December 31, 2019. During the same period in 2018, we recorded $3.4 million in product revenue and $29,000 in other revenue. The decrease in revenue is related to our entering into the licensing agreement with medac which is discussed above in the section titled “Market Access and Commercial Clinical Adoption.” Upon signing the agreement, we transitioned from selling CHEMOSAT directly to centers and recognizing the full selling price of CHEMOSAT as revenue to receiving a royalty on each kit that medac sells. As a result, our revenue has decreased in 2019. This was an anticipated change and is partially offset by the upfront and milestone payments stipulated on our agreement with medac.

Cost of Goods Sold

During the year ended December 31, 2019, we recognized cost of goods sold of approximately $0.7 million related to product revenue of $1.1 million as compared to cost of goods sold of approximately $1.0 million related to product revenue of $3.4 million in the comparable prior period. The decrease in revenue is related to our entering into the licensing agreement with medac which is discussed above in the section titled “Market Access and Commercial Clinical Adoption.” As a result of the transition from direct sales to receiving a royalty, our gross margin on each CHEMOSAT unit sold has decreased significantly in 2019. This was an anticipated change and is partially offset by the upfront and milestone payments stipulated on our agreement with medac.

Selling, General and Administrative Expenses

For the year ended December 31, 2019, selling, general and administrative expenses increased to $11.3 million from $9.8 million for the year ended December 31, 2018. The increase is primarily related to $0.9 million in settlement expenses, which was a non-cash expense discussed further in Note 11 and $0.8 million in expenses related to litigation that was settled in July and August 2019.

Research and Development Expenses

For the year ended December 31, 2019, research and development expenses decreased to $9.5 million from $19.6 million for the year ended December 31, 2018. The decrease was primarily due to a reduced rate of enrollment and related professional services for the FOCUS trial as a result of the cash constraints we experienced during the first half of 2019.

Change in Fair Value of Derivative Liability

For the year ended December 31, 2019, non-cash derivative instrument income decreased to $17.5 million from $19.7 million for the year ended December 31, 2018. In 2018, the Company issued the February 2018 Warrants which were initially valued at $18.3 million, with almost all of that value being expensed during 2018. In 2019, the Company issued the 2019 Warrants with an initial fair value of $20.8 million. At December 31, 2019, the fair value of the 2019 Warrants was $3.4 million, resulting in a $17.4 million change in the fair value.

Loss on issuance of financial instrument

For the for the year ended December 31, 2019, non-cash loss on issuance of financial instrument decreased to $1.7 million from $2.8 million for the year ended December 31, 2018. In 2019, the $1.7 million loss is related to the issuance of the $2.0 million convertible note which was issued in exchange for the cancellation of the Series D and Pre-Funded Series D Warrants discussed further in Notes 10 and 11. In 2018, the $2.8 million loss was related to the initial fair value of the Series D Warrants discussed further in Notes 10 and 11.

Other Income/Expense and Interest Expense

Other expense and interest expense are primarily related to the amortization of debt discounts discussed in Note 10 of our audited consolidated financial statements, as well as foreign currency exchange gains and losses.

Interest income is from a money market account and interest earned on operating accounts.

Net Loss

We had a net loss for the year ended December 31, 2019 of $8.9 million, a decrease of $10.3 million, or 53.8%, compared to a $19.2 million net loss for the same period in 2018. This decrease is due in part to a $8.7 million decrease in operating expenses and a $1.5 million decrease in gross profits, as well as a $5.4 million decrease in various non-cash expense items primarily related to the amortization of debt discounts and other costs related to convertible notes and other instruments issued in 2018 and 2019, and discussed in greater detail in Note 10 of the Company’s audited consolidated financial statements contained in this Annual Report on Form 10-K and a $2.2 million decrease in derivative instrument income, also a non-cash item.

Income Taxes

The Company has not recorded expense related to income taxes for the years ending December 31, 2019 and 2018, respectively, due to being in a net tax operating loss position for each of those years.

On December 22, 2017, the 2017 Tax Cuts and Jobs Act (the "Tax Act") was enacted into law and the new legislation contains several key tax provisions that affected the Company, including a one-time mandatory transition tax on accumulated foreign earnings and a reduction of the corporate income tax rate to 21% effective January 1, 2018, among others. The Company was required to recognize the effect of the tax law changes in the period of enactment, such as determining the transition tax, remeasuring our U.S. deferred tax assets and liabilities as well as reassessing the net realizability of our deferred tax assets and liabilities. In December 2017, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ("SAB 118"), which allowed the Company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Since the Tax Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation were expected in 2018, the Company considered the accounting of deferred tax re-measurements and the transition tax to be incomplete due to the forthcoming guidance and our ongoing analysis of final year-end data and tax positions. However, during the year ended December 31, 2017 the Company was able to determine a provisional amount of $143,500 (offset by valuation allowance) and $0, respectively, related to the deferred tax re-measurement and one-time transition tax. See Note 14 to the Company's audited consolidated financial statements contained in this Annual Report on Form 10-K. The Company finalized its accounting of the effects of tax reform in 2018, which resulted in insignificant adjustments.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Application of Critical Accounting Policies

The Company's consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP"). Certain accounting policies have a significant impact on amounts reported in the consolidated financial statements. A summary of those significant accounting policies can be found in Note 3 to the Company's audited consolidated financial statements contained in this Annual Report on Form 10-K.

The Company considers the valuation allowance for the deferred tax assets to be a significant accounting estimate. A valuation allowance has been recorded against the Company's deferred tax assets as management believes it is more likely than not that the deferred tax assets will not be realized. In assessing whether it is more likely than not that the Company will realize the benefits of its deferred tax assets, management considers all forms of available evidence, including the Company's history of cumulative losses, estimates of future taxable income and losses (including reversals of deferred tax liabilities), and available tax planning strategies. Since the Company is in a cumulative loss position, it cannot rely on future taxable income as a source of taxable income because the Company views a cumulative loss position as significant objective negative evidence that would be difficult to overcome with the other subjective tests discussed. The Company does not have taxable income in prior years to absorb the carryback of net operating losses, nor has it implemented tax-planning strategies that would, if necessary, be implemented to allow for the usage of net operating losses.

Prior to ASU 2016-16, GAAP prohibited the recognition of current and deferred income taxes for intra-entity asset transfers until the asset has been sold to an outside party. ASU 2016-16 eliminates this prohibition for intra-entity transfers of assets other than inventory but retain the prohibition for intra-entity transfers of inventory. This standard is effective for public entities for fiscal years beginning after December 15, 2017. On January 1, 2012, Delcath Systems, Inc. sold a portion of its intellectual property to affiliate, Delcath Holdings Limited, resulting in a taxable gain of $15.8 million in the U.S. based on the fair market value of the intangible that was transferred. The arms-length price, which was determined in accordance with Section 482 of the Internal Revenue Code, is a significant accounting estimate. Prior to ASU 2016-2016, the gain was deferred under GAAP principles until the asset is sold outside of the consolidated financial statements. The remaining deferred gain on the intercompany sale of intangible assets is $2.0 million as of December 31, 2017. The Company adopted ASU 2016-16, effective on January 1, 2018. As a result of adoption, the Company immediately recognized the $2.0 million deferred gain and none remains as of December 31, 2018.

The Company has adopted the provisions of Accounting Standard Codification ("ASC") 718, Stock-Based Compensation, which establishes accounting for equity instruments exchanged for employee services. Under the provisions of ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). The Company expenses its share-based compensation under the accelerated method, which treats each vesting tranche as if it were an individual grant.

The Company has adopted the provisions of ASC 505-50, Equity-Based Payments to Non-Employees, which establishes accounting for equity-based payments to non-employees. Measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. Each transaction is reviewed to determine the more reliably measurable basis for the valuation. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests. Non-employee stock-based compensation charges are amortized over the vesting period or period of performance of the services.

The Company has adopted the provisions of ASC 820, Fair Value Measurement, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability which are typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability. See Note 12 to the Company's audited consolidated financial statements contained in this Annual Report on Form 10-K for assets and liabilities the Company has evaluated under ASC 820.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 8. Financial Statements and Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Delcath Systems, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Delcath Systems, Inc. and Subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss**,** stockholders' deficit and cash flows for the years ended December 31, 2019 and 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years ended December 31, 2019 and 2018, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has a significant working capital deficiency, has incurred significant recurring losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Accounting Principle

As discussed in Note 3 to the consolidated financial statements, the Company has changed its method of accounting for leases in 2019 due to the adoption of ASU No. 2016-02 (Topic 842), as amended, effective January 1, 2019, using the modified retrospective approach.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Marcum LLP
Marcum LLP

We have served as the Company's auditors since 2018.

New York, New York
March 25, 2020

DELCATH SYSTEMS, INC.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 10,002	$ 2,516
Restricted cash	181	1,062
Accounts receivables, net	21	585
Inventories	654	858
Prepaid expenses and other current assets	1,759	898
Total current assets	12,617	5,919
Property, plant and equipment, net	735	925
Right-of-use assets	860	—
Total assets	$ 14,212	$ 6,844
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 4,533	$ 7,715
Accrued expenses	6,947	7,964
Convertible notes payable, net of debt discount	—	2,038
Lease liabilities, current portion	664	—
Warrant liability	3,368	33
Total current liabilities	15,512	17,750
Deferred revenue	2,860	3,405
Lease liabilities, long-term portion	197	—
Convertible notes payable, net of debt discount	2,000	—
Other non-current liabilities	—	628
Total liabilities	20,569	21,783
Commitments and contingencies		
Stockholders' Deficit		
Preferred stock, $.01 par value; 10,000,000 shares authorized; 41,517 and 101 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	—	—
Common stock, $.01 par value; 1,000,000,000 shares authorized; 67,091 and 14,715 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively*	1	—
Additional paid-in capital	364,785	329,065
Accumulated deficit	(371,171)	(344,054)
Accumulated other comprehensive loss	28	50
Total stockholders' deficit	(6,357)	(14,939)
Total liabilities and stockholders' deficit	$ 14,212	$ 6,844

* reflects, a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018, and a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year ended December 31,	
	2019	2018
Product revenue	$ 1,101	$ 3,378
Other revenue	479	29
Cost of goods sold	(719)	(1,009)
Gross profit	861	2,398
Operating expenses:		
Research and development expenses	9,490	19,650
Selling, general and administrative expenses	11,279	9,819
Total operating expenses	20,769	29,469
Operating loss	(19,908)	(27,071)
Change in fair value of the warrant liability, net	17,493	19,706
Loss on debt extinguishment	—	(1,123)
Loss on issuance of financial instrument	(1,720)	(2,826)
Interest expense	(4,746)	(7,959)
Other income	2	51
Net loss	$ (8,879)	$ (19,222)
Other comprehensive loss:		
Foreign currency translation adjustments	$ (22)	$ 8
Comprehensive loss	$ (8,901)	$ (19,214)
Common share data:		
Basic and diluted loss per share*	$ (1,047)	$ (504)
Weighted average number of basic and diluted shares outstanding*	25,900	38,151

* reflects, a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018, and a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Consolidated Statements of Stockholders' Deficit
(in thousands, except share data)

	Common Stock $0.01 Par Value		Preferred Stock $0.01 Par Value					
	No. of Shares	Amount	No. of Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
Balance at January 1, 2019	**14,715**	**$ —**	**101**	**$ —**	**$ 329,065**	**$ (344,054)**	**$ 50**	**$ (14,939)**
Compensation expense for issuance of stock options	—	—	—	—	273	—	—	273
Compensation expense for issuance of restricted stock	20	—	—	—	4	—	—	4
Issuance of Series D Preferred Stock	—	—	15	—	150	—	—	150
Retirement of Series D Preferred Stock	—	—	(116)	—	(1,160)	—	—	(1,160)
Exercise of Pre-Funded Series D Warrants	11,285	—	—	—	—	—	—	—
Exchange of warrants	92	—	—	—	13	—	—	13
Issuance of Series E Preferred Stock	—	—	32,572	—	42,876	(13,340)	—	29,536
Issuance of Series E-1 Preferred Stock	—	—	9,510	—	14,408	(4,898)	—	9,510
Fair value of warrants issued	—	—	—	—	(20,844)	—	—	(20,844)
Conversion of Preferred stock into common stock	13,455	—	(565)	—	1	—	—	1
Shares issued due to fractional rounding upon reverse stock split	27,524	1	—	—	(1)	—	—	—
Net loss	—	—	—	—	—	(8,879)	—	(8,879)
Total comprehensive loss	—	—	—	—	—	—	(22)	(22)
Balance at December 31, 2019	**67,091**	**$ 1**	**41,517**	**$ —**	**364,785**	**$ (371,171)**	**28**	**$ (6,357)**

	Common Stock Issued $0.01 Par Value		Preferred Stock $0.01 Par Value		Treasury Stock					
	No. of Shares	Amount	No. of Shares	Amount	No. of Shares	Amount	Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at January 1, 2018	**377**	**$ —**	**—**	**$ —**	**(1)**	**$ (51)**	**$ 325,519**	**$ (324,832)**	**$ 42**	**$ 678**
Compensation income related to cancellation of stock options	—	—	—	—	—	—	(40)	—	—	(40)
Compensation expense for issuance of restricted stock	236	—	—	—	—	—	98	—	—	98
Sale of common stock, net of expenses	7,624	—	—	—	—	—	10,916	—	—	10,916
Fair value of warrants issued	—	—	—	—	—	—	(18,306)	—	—	(18,306)
Cashless exercise of warrants	49	—	—	—	—	—	—	—	—	—
Issuance of pre-funded warrants	—	—	—	—	—	—	520	—	—	520
Exercise of pre-funded warrants	5,250	—	—	—	—	—	—	—	—	—
Fair value of warrants issued with Convertible Notes	—	—	—	—	—	—	5,007	—	—	5,007
Fair value of warrants reclassified from liability to equity	—	—	—	—	—	—	4,210	—	—	4,210
Beneficial conversion feature of convertible note	—	—	—	—	—	—	44	—	—	44
Issuance of Series D Preferred Stock	—	—	101	—	—	—	1,004	—	—	1,004
Exchange of warrants for Common Stock	1,179	—	—	—	—	—	—	—	—	—
Fair value of warrants exchanged for Common Stock	—	—	—	—	—	—	144	—	—	144
Retirement of Treasury Stock	—	—	—	—	1	51	(51)	—	—	—
Net income	—	—	—	—	—	—	—	(19,222)	—	(19,222)
Total comprehensive loss	—	—	—	—	—	—	—	—	8	8
Balance at December 31, 2018	**14,715**	**$ —**	**101**	**$ —**	**—**	**$ —**	**$ 329,065**	**$ (344,054)**	**$ 50**	**$ (14,939)**

* reflects, a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018, and a one-for-seven hundred (1:700) reverse stock split effected on December 24, 2019.

See Accompanying Notes to these Consolidated Financial Statements.

DELCATH SYSTEMS, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year ended December 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (8,879)	$ (19,222)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense (income)	273	(40)
Restricted stock compensation expense	4	98
Depreciation expense	212	444
Amortization of Right of Use Asset	1,577	—
Warrant liability fair value adjustment	(17,493)	(19,706)
Non-cash interest income	(11)	(1)
Equitization of expenses	1,474	—
Loss on issuance of financial instrument	1,715	402
Interest expense accrued related to convertible notes	74	7,572
Debt discount amortization	4,467	2,826
Loss on debt settlements	—	1,123
Changes in assets and liabilities:		—
Prepaid expenses and other assets	(367)	(218)
Accounts receivable	497	(293)
Inventory	204	385
Accounts payable and accrued expenses	(4,791)	8,163
Deferred revenue	(479)	3,503
Interest payments on financing lease	(3)	—
Operating lease liability	(1,537)	—
Other non-current liabilities	(627)	232
Net cash used in operating activities	(23,690)	(14,732)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(24)	(76)
Net cash used in investing activities	(24)	(76)
Cash flows from financing activities:		
Repayment of convertible note debt	—	(4,870)
Net proceeds from the issuance of debt	3,719	—
Net proceeds from the sale of Series E and E-1 Preferred Stock and warrants	26,475	—
Net proceeds from sale of Series D preferred shares	150	1,005
Principal payments of financing leases	(39)	—
Net proceeds from convertible note debt financing	—	5,664
Net proceeds from sale of stock	—	10,917
Net proceeds from exercise of warrants	—	520
Net cash provided by financing activities	30,305	13,236
Foreign currency effects on cash, cash equivalents and restricted cash	14	(174)
Net increase (decrease) in cash, cash equivalents and restricted cash	6,605	(1,746)
Cash, cash equivalents and restricted cash:		
Beginning of period	3,578	5,324
End of period	$ 10,183	$ 3,578
Supplemental non-cash activities:		
Fair value of warrants issued	$ 20,844	$ 28,539
Reclassification of Series D Warrants from liability to equity	$ —	$ 4,210
Equitization of debt, interest and expenses into July 2019 Private Placement	$ 12,572	$ —
Adoption of ASC 842 lease standard	$ 1,652	$ —
Right of use assets obtained in exchange for lease obligations	$ 874	$ —
Financing of insurance	$ 548	$ —

See Accompanying Notes to these Consolidated Financial Statements.

(1) Description of Business

We are an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our lead product candidate, Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System, or Melphalan/HDS, is designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, Melphalan/HDS is approved for sale under the trade name Delcath CHEMOSAT ® Hepatic Delivery System for Melphalan, or CHEMOSAT.

Our primary research focus is on ocular melanoma liver metastases, or mOM, and intrahepatic cholangiocarcinoma, or ICC, a type of primary liver cancer, as well as certain other cancers that are metastatic to the liver. We believe that the disease states we are investigating are unmet medical needs that represent significant market opportunities.

In the United States, Melphalan/HDS is considered a combination drug and device product and is regulated as a drug by the United States Food and Drug Administration, or the FDA. The FDA has granted us six orphan drug designations, including three orphan designations for the potential use of the drug melphalan for the treatment of patients with mOM, hepatocellular carcinoma and ICC. Melphalan/HDS has not been approved for sale in the United States.

In Europe, our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are commercializing the CHEMOSAT system in select markets in the United Kingdom and the European Union, or EU, where we believe the prospect of securing reimbursement coverage for the use of CHEMOSAT is strongest.

Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying consolidated financial statements during the year ended December 31, 2019, the Company incurred net operating losses of $8.9 million and used $23.7 million of cash for its operating activities. These factors among others raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time.

The Company's existence is dependent upon management's ability to obtain additional funding sources or to enter into strategic alliances. Adequate additional financing may not be available to us on acceptable terms, or at all. If the Company is unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, it would be forced to delay, reduce or eliminate our research and development programs or any commercialization efforts. There can be no assurance that the Company's efforts will result in the resolution of the Company's liquidity needs. If Delcath is not able to continue as a going concern, it is likely that holders of its common stock will lose all of their investment. The accompanying consolidated financial statements do not include any adjustments that might result should the Company be unable to continue as a going concern.

The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. At December 31, 2019, management believed that its capital resources were adequate to fund operations through June 2020. Additional working capital will be required to continue operations. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainty of product development and clinical trial results; uncertainty regarding regulatory approval; technological uncertainty; uncertainty regarding patents and proprietary rights; comprehensive government regulations; limited commercial manufacturing, marketing or sales experience; and dependence on key personnel.

(2) Basis of Consolidated Financial Statement Presentation

The accounting and financial reporting policies of the Company conform to generally accepted accounting principles in the United States of America ("GAAP"). The preparation of consolidated financial statements in conformity with GAAP requires management to make assumptions and estimates that impact the amounts reported in the Company's consolidated financial statements. The consolidated financial statements include the accounts of all entities controlled by Delcath. All significant inter-company accounts and transactions are eliminated.

Reverse Stock Splits

All share numbers presented in these financial statements, including these footnotes reflect a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018 and a one-for seven hundred (1:700) reverse stock split effected on December 24, 2019.

(3) Summary of Significant Accounting Policies

Use of Estimates

The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's consolidated balance sheets and the amount of revenues and expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, the accounting for derivative instrument liabilities, stock-based compensation, valuation of inventory, impairment of long-lived assets, income taxes and operating expense accruals. Such assumptions and estimates are subject to change in the future as additional information becomes available or as circumstances are modified. Actual results could differ from these estimates.

Cash Equivalents and Concentrations of Credit Risk

The Company considers investments with original maturities of three months or less at date of acquisition to be cash equivalents. The Company has deposits that exceed amounts insured by the Federal Deposit Insurance Corporation ("FDIC"), however, the Company does not consider this a significant concentration of credit risk based on the strength of the financial institution.

Restricted Cash

Cash and cash equivalents that are restricted as to withdrawal or use under the terms of certain contractual agreements are recorded as restricted cash on the accompanying consolidated balance sheets.

Accounts Receivable

Accounts receivable, principally trade, are generally due within 30 days and are stated at amounts due from customers. Collections and payments from customers are monitored and a provision for estimated credit losses may be created based upon historical experience and specific customer collection issues that may be identified.

Inventories

Inventories are valued at the lower of cost or net realizable value using the first-in, first-out method. The reported net value of inventory includes finished saleable products, work-in-process, and raw materials that will be sold or used in future periods. The Company reserves for expired, obsolete, and slow-moving inventory.

Property, Plant and Equipment

Property, plant and equipment are recorded at cost, less accumulated depreciation. The Company provides for depreciation on a straight line basis over the estimated useful lives of the assets which range from three to seven years. Leasehold improvements will be amortized over the shorter of the lease term or the estimated useful life of the related assets when they are placed into service. The Company evaluates property, plant and equipment for impairment periodically to determine if changes in circumstances or the occurrence of events suggest the carrying value of the asset or asset group may not be recoverable. Maintenance and repairs are charged to operations as incurred. Expenditures which substantially increase the useful lives of the related assets are capitalized.

Derivative Instrument Liability

The Company accounts for derivative instruments in accordance with Accounting Standards Codification ("ASC") 815, Derivatives and Hedging, which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value, regardless of the hedging relationship designation. Accounting for changes in the fair value of the derivative instruments depends on whether the derivatives qualify as hedge relationships and the types of relationships designated are based on the exposures hedged. At December 31, 2019 and 2018, the Company did not have any derivative instruments that were designated as hedges.

Fair Value Measurements

The Company adheres to ASC 820, Fair Value Measurement, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. ASC 820 applies to reported balances that are required or permitted to be measured at fair value under existing accounting pronouncements; accordingly, the standard does not require any new fair value measurements of reported balances.

ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

- Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals.
- Level 3 inputs are unobservable inputs for the asset or liability, which is typically based on an entity's own assumptions, as there is little, if any, related market activity.

In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability.

Revenue Recognition

Revenue is generated from proprietary and partnered product sales and license and royalty arrangements. Revenue is recognized when or as we transfer control of the promised goods or services to our customers in an amount that reflects the consideration to which we expect to be entitled to in exchange for those goods or services. When obligations or contingencies remain after the products are shipped, such as training and certifying the treatment centers, revenue is deferred until the obligations or contingencies are satisfied.

We may enter into contracts with partners that contain multiple elements such as licensing, development, manufacturing and commercialization components. These arrangements are often complex and we may receive various types of consideration over the life of the arrangement, including: up-front fees, reimbursements for research and development services, milestone payments, payments on product shipments, margin sharing arrangements, license fees and royalties.

Our results of operations for reporting periods beginning on or after January 1, 2018 are presented under ASC 606, Revenue from Contracts with Customers, while prior period amounts, as reported, are not adjusted. The effects of the adoption of the new standard in 2018 were not material to our consolidated financial statements. In assessing our revenue arrangements in accordance with ASC 606, Revenue from Contracts with Customers, we must identify the contract, determine the transaction price including an estimation of any variable consideration we expect to receive in connection with the contract, identify the promises of goods or services to the customer and each distinct performance obligation, allocate the transaction price to each of the performance obligations, and recognize revenue when or as the performance obligations are satisfied. Each of these steps in the revenue recognition process requires management to make judgements and/or estimates. The most significant judgements and estimates involve the determination of variable consideration to be included in the transaction price. Variable consideration is recognized at an amount we believe is not subject to significant reversal and is adjusted at each reporting period if the most likely amount of expected consideration changes or becomes fixed. We believe this provides a reasonable basis for recognizing revenue, however, actual results could differ from estimates and significant changes in estimates could impact our results of operations in future periods.

Deferred Revenue

License fees and milestones received in exchange for the grant of a license for the commercialization of CHEMOSAT are generally recognized over the development period, as the license is considered distinct from the delivery of product. Milestone payments that are contingent upon the occurrence of future events, are evaluated and recorded at the most likely amount, and to the extent that it is probable that a significant reversal will not occur when the associated uncertainty is resolved.

Selling, General and Administrative

Selling, general and administrative costs include personnel costs and related expenses for the Company's sales, marketing, general management and administrative staff, recruitment, costs related to the Company's commercialization efforts in Europe, professional service fees, professional license fees, business development and certain general legal activities. All such costs are charged to expense when incurred.

Research and Development

Research and development costs include the costs of materials used for clinical trials and R&D, personnel costs associated with device and pharmaceutical R&D, clinical affairs, medical affairs, medical science liaisons, and regulatory affairs, costs of outside services and applicable indirect costs incurred in the development of the Company's proprietary drug delivery system. All such costs are charged to expense when incurred.

Stock Based Compensation

The Company accounts for its share-based compensation in accordance with the provisions of ASC 718, Stock-Based Compensation, which establishes accounting for equity instruments exchanged for employee services and ASC 505-50, Equity-Based Payments to Non-Employees, which establishes accounting for equity-based payments to non-employees. Under the provisions of ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). The Company is required to record compensation cost for all share-based payments granted to employees based upon the grant date fair value, estimated in accordance with the provisions of ASC 718. Under the provisions of ASC 505-50, measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests. The Company expenses its share-based compensation for share-based payments granted under the accelerated method, which treats each vesting tranche as if it were an individual grant.

The Company periodically grants stock options for a fixed number of shares of common stock to its employees, directors and non-employee contractors, with an exercise price greater than or equal to the fair market value of Delcath's common stock at the date of the grant. The Company estimates the fair value of stock options using an option pricing model. Key inputs used to estimate the fair value of stock options include the exercise price of the award, the expected post-vesting option life, the expected volatility of Delcath's stock over the option's expected term, the risk-free interest rate over the option's expected term, and Delcath's expected annual dividend yield. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

Income Taxes

The Company accounts for income taxes following the asset and liability method in accordance with the ASC 740, Income Taxes. Under such method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The Company applies the accounting guidance issued to address the accounting for uncertain tax positions. This guidance clarifies the accounting for income taxes, by prescribing a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements as well as provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company classifies interest and penalty expense related to uncertain tax positions as a component of income tax expense. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years that the asset is expected to be recovered or the liability settled. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets depends on the generation of future taxable income during the period in which related temporary differences become deductible. The Company considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in its assessment of a valuation allowance. See Note 14 for additional information.

Net Loss per Common Share

Basic net loss per share is determined by dividing net loss by the weighted average shares of common stock outstanding during the period, without consideration of potentially dilutive securities except for those shares that are issuable for little or no cash consideration. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as stock options and warrants calculated using the treasury stock method. In periods with reported net operating losses, all common stock options and warrants are generally deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal. However, in certain periods in which the exercise price of the warrants was less than the last reported sales price of Delcath's common stock on the final trading day of the period and there is a gain recorded pursuant to the change in fair value of the warrant derivative liability, the impact of gains related to the mark-to-market adjustment of the warrants outstanding at the end of the period is reversed and the treasury stock method is used to determine diluted earnings per share. As discussed in Note 11, the Series E Preferred Stock and the Series E-1 Preferred Stock were each determined to have a beneficial conversion feature which was accounted for as a deemed dividend.

For the years ended December 31, 2019 and 2018 the following potentially dilutive securities were excluded from the computation of diluted earnings per share because their effects would be antidilutive:

	2019	2018
Common stock warrants - equity	—	6,005
Common stock warrants - liability	1,826,608	271
Assumed conversion of Series E and Series E-1 Preferred Stock	1,802,008	—
Assumed conversion of convertible notes	63,493	3,681
Stock options	1,640	—
Total	3,693,749	9,957

Segment Information

The Company currently operates in one business segment, which is the development and commercialization of Melphalan/HDS and CHEMOSAT. A single management team that reports to the CEO and President comprehensively manages the business. Accordingly, the Company does not have separately reportable segments.

Foreign Currency and Currency Translation

Transactions that are denominated in a foreign currency are remeasured into the functional currency at the current exchange rate on the date of the transaction. Any foreign currency-denominated monetary assets and liabilities are subsequently remeasured at current exchange rates, with gains or losses recognized as foreign exchange (losses)/gains in the statements of operations.

The assets and liabilities of the Company's international subsidiaries are translated from their functional currencies into United States dollars at exchange rates prevailing at the balance sheet date. The majority of the foreign subsidiaries revenues and operating expenses are denominated in Euros. The reporting currency for the Company is the United States Dollar ("USD"). Average rates of exchange during the period are used to translate the statement of operations, while historical rates of exchange are used to translate any equity transactions.

Translation adjustments arising on consolidation due to differences between average rates and balance sheet rates, as well as unrealized foreign exchange gains or losses arising from translation of intercompany loans that are of a long-term-investment nature, are recorded in other comprehensive income.

Recently Adopted Accounting Pronouncements

In February 2018, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2018-02, Income Statement—Reporting Comprehensive Income (Topic 220). ASU 2018-02 allows a company to elect a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. ASU 2018-02 is effective for periods beginning after December 15, 2018. Upon adoption of ASU 2018-02, the Company did not elect to reclassify the tax effects of the Tax Cuts and Jobs Act from accumulated other comprehensive income to retained earnings, as the stranded tax effects were insignificant.

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)* ("ASC 842"). In July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Topic 842, Leases* ("ASU 2018-10"), which provides narrow amendments to clarify how to apply certain aspects of the new lease standard, and ASU No. 2018-11, *Leases (Topic 842)—Targeted Improvements* ("ASU 2018-11"), which addressed implementation issues related to the new lease standard. These and certain other lease-related ASUs have generally been codified in ASC 842. ASC 842 supersedes the lease accounting requirements in ASC Topic 840, *Leases* ("ASC 840"). ASC 842 establishes a right-of-use model that requires a lessee to record a right-of-use ("ROU") asset and a lease liability on the balance sheet for all leases. Under ASC 842, leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The standard also requires disclosures to help investors and other financial statement users better understand the amount, timing and uncertainty of cash flows arising from leases. ASU 2016-02 was effective for annual reporting periods beginning after December 15, 2018 and interim periods within that reporting period. The Company adopted ASC 842 on January 1, 2019 using the effective date transition method. Prior period results continue to be presented under ASC 840 based on the accounting standards originally in effect for such periods.

The Company has elected certain practical expedients permitted under the transition guidance within ASC 842 to leases that commenced before January 1, 2019, including the package of practical expedients. The election of the package of practical expedients resulted in the Company not reassessing prior conclusions under ASC 840 related to lease identification, lease classification and initial direct costs for expired and existing leases prior to January 1, 2019. The Company did not elect the practical expedient to not record short-term leases on its consolidated balance sheet. The adoption of ASU 2016-02 did not have a significant impact on the Company's consolidated results of operations or cash flows. See Note 9 for additional information.

SEC Disclosure Update and Simplification

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the

amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule was effective on November 5, 2018. The adoption did not have a material impact on the Company's consolidated financial statements.

(4) Restricted Cash

Cash and cash equivalents that are restricted as to withdrawal or use under the terms of certain contractual agreements are recorded in *Restricted Cash* on the balance sheet. Restricted cash does not include required minimum balances.

(in thousands)	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 10,002	$ 2,516
Convertible Notes	—	—
Letters of credit	131	1,012
Security for credit cards	50	50
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 10,183	$ 3,578

(5) Inventories

Inventories consist of:

(in thousands)	December 31, 2019	December 31, 2018
Raw materials	$ 375	$ 358
Work-in-process	279	500
Finished goods	—	—
Total Inventory	$ 654	$ 858

(6) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets include the following:

(in thousands)	December 31, 2019	December 31, 2018
Clinical trial expenses	725	—
Insurance premiums	589	140
Security deposit	51	51
Income tax and VAT receivable	31	579
Other[1]	363	128
Total prepaid expenses and other current assets	$ 1,759	$ 898

[1]Other consists of various prepaid expenses and other current assets, with no individual item accounting for more than 5% at December 31, 2019 and 2018.

(7) Property, Plant, and Equipment

Property, plant, and equipment consists of:

(in thousands)	December 31, 2019	December 31, 2018	Estimated Useful Life
Buildings and land	$ 589	$ 589	30 years - Buildings
Enterprise hardware and software	1,739	1,742	3 years
Leaseholds	1,695	1,701	Lesser of lease term or estimated useful life
Equipment	1,025	1,002	7 years
Furniture	198	198	5 years
Property, plant and equipment, gross	5,246	5,232	
Accumulated depreciation	(4,511)	(4,307)	
Property, plant and equipment, net	$ 735	$ 925	

Depreciation expense for the years ended December 31, 2019 and 2018 was $0.2 million and $0.4 million, respectively.

(8) Accrued Expenses

Current accrued expenses include the following:

(in thousands)	December 31, 2019	December 31, 2018
Clinical trial expenses	$ 2,497	$ 4,530
Compensation, excluding taxes	3,525	1,785
Professional fees	263	190
Short-term portion of lease restructuring	-	184
Other[1]	662	1,275
Total accrued expenses	$ 6,947	$ 7,964

[1]Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at December 31, 2019 and 2018.

(9) Leases

The Company recognizes right-of-use (“ROU”) assets and lease liabilities when it obtains the right to control an asset under a leasing arrangement with an initial term greater than twelve months. The Company leases its facilities under non-cancellable operating and financing leases.

The Company evaluates the nature of each lease at the inception of an arrangement to determine whether it is an operating or financing lease and recognizes the ROU asset and lease liabilities based on the present value of future minimum lease payments over the expected lease term. The Company’s leases do not generally contain an implicit interest rate and therefore the Company uses the incremental borrowing rate it would expect to pay to borrow on a similar collateralized basis over a similar term in order to determine the present value of its lease payments.

The following table summarizes the Company’s operating and financing leases as of December 31, 2019:

(in thousands)	US	Ireland	Total
Lease Cost			
Operating lease cost	$ 710	$ 210	$ 920
Financing lease cost	42	—	42
Sublease income	(215)	(175)	(390)
Total	$ 537	$ 35	$ 572
Other information			
Operating cash flows out from operating leases	(755)	(210)	(965)
Operating cash flows in from operating leases	215	175	390
Operating cash flows out from financing leases	(39)	—	(39)
Right-of-use assets exchanged for new operating lease liabilities	874	—	874
Weighted average remaining lease term	1.1	1.8	
Weighted average discount rate - operating leases	8%	8%	

Maturities of the Company's operating leases, excluding short-term leases, are as follows:

(in thousands)	US	Ireland	Total
Year ended December 31, 2020	$ 498	$ 210	$ 708
Year ended December 31, 2021	79	122	201
Total	577	332	909
Less present value discount	(27)	(21)	(48)
Operating lease liabilities included in the condensed consolidated balance sheet at December 31, 2019	$ 550	$ 311	$ 861

(10) Outstanding Debt

On June 6, 2019, the Company entered into an agreement with two institutional investors, pursuant to which the investors agreed to transfer and surrender warrants to purchase 5,605 shares of the Company's common stock (the "Series D Warrants") and warrants to purchase 0.1 million shares of the Company's common stock (the "Pre-Funded Series D Warrants") for cancellation by the Company. Under the terms of the Purchase Agreement, the Company agreed to sell and issue to the investors 8% Senior Secured Promissory Notes in an aggregate principal amount of $2.0 million in full payment and satisfaction of the purchase price for the Series D Warrants and Pre-Funded Series D Warrants. This agreement was effective on July 15, 2019, upon the closing of the Company's Private Placement discussed further in Note 11. Following the closing of the Private Placement, the Company entered into an agreement under which the 8% Senior Secured Promissory Notes became convertible into shares of Series E Preferred Stock and Warrants at the price of $1,500 per Unit. The principal is recognized in Convertible notes payable, long-term on the consolidated balance sheet.

On April 19, 2019, April 26, 2019, May 9, 2019 and May 23, 2019, the Company issued 8% senior secured notes (collectively, the "2019 Notes") in the aggregate principal amount of $3.3 million, to two institutional investors. The 2019 Notes bore interest at the rate of 8% per annum and were to mature on the six-month anniversary of issuance in each case. The 2019 Notes were not convertible. The 2019 Notes contained standard events of default and remedies and are secured by a lien on the Company's assets. The 2019 Notes were exchanged as part of the recent equity financing discussed further in Note 11 and are no longer outstanding.

In March 2019, the Company exchanged all issued and outstanding shares of its Series D Preferred Stock (having an aggregate stated value of $1,160,000) and received $400,000 in cash proceeds in exchange for a senior secured promissory note (the "March 2019 Note") in the principal amount of $1,560,000. The March 2019 Note bore interest at the rate of 8% per annum, and were to mature on April 1, 2020, and was not convertible. The March 2019 Note was exchanged as part of the recent equity financing discussed further in Note 9 and is no longer outstanding.

On June 4, 2018, July 21, 2018, August 29, 2018, and September 21, 2018, the Company issued 8% senior secured convertible notes (collectively, the "2018 Notes") in the aggregate principal amount of $9.4 million to several institutional investors. The

2018 Notes bore interest at the rate of 8% per annum and had maturity dates between December 2018 and March 2021. The 2018 Notes were initially convertible and secured pursuant to a Security Agreement which created a first priority security interest in all of the personal property (other than Excluded Collateral as defined in the Security Agreement) of the Company of every kind and description, tangible or intangible, whether currently owned and existing or created or acquired in the future. In March 2019, the Company amended the June 2018, July 2018 and August 2018 Notes to make them non-convertible. There was no impact to the financial statements. In April 2019, the Company received notices of default from the investors in the 2018 Notes which resulted in a 25%, or $1.1 million, increase in principal and an increase in the interest rates from 8% to 18%. The 2018 Notes were exchanged as part of the recent equity financing discussed further in Note 9 and are no longer outstanding.

The following table provide a summary of the outstanding Note at December 31, 2019:

(in millions)	Conversion price	Current interest rate	Principal
Long term convertible notes payable			
8.0% July 2019 Notes	$ 1,500	8%	$ 2.0

The following table provides a summary of the Notes by their maturity dates (absent provisions of default) at December 31, 2018:

(in millions)	Interest rate	Conversion price	Principal	Unamortized Discount	Carrying value
December 4, 2018	8.0%	$ 1.75	$ 1.7	$ —	$ 1.7
March 1, 2019	8.0%	1.75	0.6	(0.5)	0.1
March 21, 2019	8.0%	1.75	0.4	(0.2)	0.2
December 4, 2019	8.0%	1.75	0.9	(0.9)	—
March 1, 2020	8.0%	1.75	0.8	(0.8)	—
March 21, 2020	8.0%	1.75	0.1	(0.1)	—
Total Convertible Notes Payable, net			$ 4.5	$ (2.5)	$ 2.0

(11) Stockholders' Equity

Preferred Stock Issuances

Series E and Series E-1 Preferred Stock

On July 11, 2019, the Company entered into a securities purchase agreement with certain accredited investors pursuant to which Delcath sold to investors an aggregate of 20,000 shares of our Series E convertible preferred stock, par value $0.01 per share, or the Series E Preferred Stock, at a price of $1,000 per share and a warrant, or a 2019 E Warrant, to purchase a number of shares of common stock equal to the number of shares of common stock issuable upon conversion of the Series E Preferred Stock purchased by the investor, or the July 2019 Private Placement. In connection with the July 2019 Private Placement, the Company exchanged $11.8 million of debt, interest and Series D Warrants for 11,500 shares of Series E Preferred Stock and related 2019 Warrants, $0.1 million in accounts payables for 149 shares of Series E Preferred Stock and related 2019 Warrants and issued 923 shares of Series E Preferred Stock and related 2019 Warrants to certain investors in exchange for a waiver of rights under exchange agreements signed in December 2018 and March 2019, or the Debt Exchange.

On August 19, 2019, the Company entered into a securities purchase agreement with certain accredited investors pursuant to which Delcath sold to investors an aggregate of 9,510 shares of Series E-1 convertible preferred stock, par value $0.01 per share, or the Series E-1 Preferred Stock, at a price of $1,000 per share and a warrant, or a 2019 E-1 Warrant, and together with the 2019 E Warrant, the 2019 Warrants, to purchase a number of shares of common stock of the Company equal to the number of shares of common stock issuable upon conversion of the Series E-1 Preferred Stock purchased by the investor, or the August 2019 Private Placement, and, collectively with the July 2019 Private Placement, the Private Placements.

Each share of Series E Preferred Stock and Series E-1 Preferred Stock, or, collectively, the Preferred Stock, was originally convertible at any time at the option of the holder into the number of shares of common stock determined by dividing the stated

value by the conversion price of $42.00, subject to certain limitations and adjustments, or the Conversion Price. Except for certain adjustments, the holders of the Preferred Stock are entitled to receive dividends on shares of Preferred Stock equal (on an "as converted" basis) to and in the same form as dividends paid on shares of the common stock. Any such dividends that are not paid to the holders of the Preferred Stock will increase the stated value. No other dividends will be paid on shares of Preferred Stock. Each 2019 Warrant had an original exercise price equal to $42.00, subject to adjustment in accordance with the terms of the 2019 Warrants, or the Exercise Price, and became exercisable at any time upon the consummation of the Reverse Split and will be exercisable until 5:00 p.m. (NYC time) on the date that is five years following the date of the Reverse Split.

Pursuant to the terms of the Preferred Stock and the 2019 Warrants, the Conversion Price of the Preferred Stock and the Exercise Price of the 2019 Warrants were initially subject to adjustment in each of the following circumstances: (i) on the third trading day following the date that the Company effects a reverse stock split, or the Reverse Split Reset Date, (ii) the date that the initial registration statement covering the shares of common stock issuable upon the conversion of the Preferred Stock and the exercise of the 2019 Warrants is declared effective by the SEC, or the Registration Reset Date, and (iii) in the event that all of the shares of common stock which we were required to register with the SEC were not then registered on an effective registration statement, the date that all of the shares underlying the respective Preferred Stock and 2019 Warrants may be sold pursuant to Rule 144, or the Rule 144 Reset Date, each of such reset dates, a Reset Date and, collectively, the Reset Dates. On each Reset Date, the Conversion Price and the Exercise Price were to be reduced, and only reduced, to equal the lesser of (x) the then effective Conversion Price or Exercise Price, as applicable, and (y) 90% of the average of the five daily volume weighted average prices of the common stock immediately prior to each Reset Date, or the Reset Formula. In the event of a reduction in the Exercise Price, the aggregate number of Warrant Shares issuable upon the exercise of the 2019 Warrants were to be increased such that the aggregate Exercise Price of the Warrants on the day immediately following such Reset Date equaled the aggregate Exercise Price immediately prior to such adjustment. In addition, from the date of issuance of the Preferred Stock and Warrants until such time that the Company's common stock is listed or quoted on a national exchange, the Conversion Price and the Exercise Price are subject to price-based anti-dilution protections.

The Registration Reset Date occurred on November 7, 2019. However, pursuant to the Reset Formula, no reduction in the Conversion Price or the Exercise Price occurred on the Registration Reset Date. The Reverse Split Reset Date occurred on December 30, 2019. Pursuant to the Reset Formula, the Conversion Price and the Exercise Price were reduced to $23.04 per share as of the Reverse Split Reset Date. The Rule 144 Reset Date with respect to the Series E Preferred Stock and the Series E Warrants occurred on January 15, 2020, but no reset in the Conversion Price or the Exercise Price of the Series E Preferred Stock or the Series E Warrants occurred as of such date because all of the shares of common stock issuable in respect of such securities had been registered for resale. The Rule 144 Reset Date with respect to the Series E-1 Preferred Stock and the Series E-1 Warrants occurred on February 19, 2020, but no reset in the Conversion Price or the Exercise Price of the Series E-1 Preferred Stock or the Series E-1 Warrants occurred as of such date because all of the shares of common stock issuable in respect of such securities had been registered for resale.

As a consequence of the reduction of the Conversion Price on the Reverse Split Reset Date, an additional 813,473 shares of common stock became issuable upon the conversion of the Preferred Stock and, as a consequence of the reduction of the Exercise Price on the Reverse Split Reset Date, an additional 824,587 shares of common stock became issuable upon the exercise of the 2019 Warrants, or collectively the Reset Shares. Pursuant to the terms of the registration rights agreements entered into in connection with the Private Placements and the Debt Exchange we were required to register a number of shares of our common stock that would be issuable assuming that the Conversion Price and the Exercise Price were $16.10 per share, regardless of the actual Conversion Price or the Exercise Price. Pursuant to that requirement, we registered a total of 3,429,680 shares of common stock for sale or other disposition by the Selling Stockholders on our registration statement on Form S-1 (File No. 333-235751), or the Second Registration Statement, which included the Rosalind Shares, the Reset Shares and an additional 1,564,085 shares of our common stock, or the Registrable Shares, even though we were obligated to issue only the Reset Shares as a result of the Reverse Split. However, because the Second Registration Statement was not declared effective until January 7, 2020, the Company is liable to Rosalind for liquidated damages under the terms of the registration rights agreements relating to the Private Placements and the Debt Exchange for the period from December 28, 2019 and January 7, 2020.

The Company received net proceeds after expenses of $26.6 million. As discussed above, the Company exchanged $11.8 million of debt, interest and Series D Warrants for 11,500 shares of Series E Preferred Stock and related warrants. The Company also exchanged $0.1 million in accounts payables for 149 shares of Series E Preferred Stock and related warrants and issued 923 shares of Series E Preferred Stock and related Warrants to certain investors in exchange for a waiver of rights under exchange agreements signed in December 2018 and March 2019. Of the net proceeds and equitized value received, the Company allocated an estimated fair value of $20.8 million to the 2019 Warrants. As a result of the Series E Preferred Stock and Series E-1

Preferred Stock having an effective conversion price that was lower than the market price on the date of issuance, the Company has recognized a beneficial conversion feature of $18.3 million. Due to the Series E Preferred Stock and Series E-1 Preferred Stock being immediately convertible, the beneficial conversion feature was recognized in full as a deemed dividend.

Series D Preferred Stock

On November 5, 2018, the Company's Board authorized the establishment of a new series of preferred stock designated as Series D Preferred Stock, $0.01 par value, the terms of which are set forth in the certificate of designations for such series of Preferred Stock. On March 29, 2019, the Company exchanged all issued and outstanding shares of its Series D Preferred Stock (having an aggregate stated value of $1,160,000) and received $400,000 in cash proceeds in exchange for the issuance of the March 2019 Notes. Please see the discussion under Notes 10 and 11 above.

Common Stock Issuances

Series E and Series E-1 Convertible Preferred Stock Conversions

565 shares of Series E and Series E-1 Convertible Preferred Stock were converted into 13,455 shares of common stock, $0.01 par value per share, during 2019.

Pre-Funded Series D Warrant Exercises

5,379 Pre-Funded Series D Warrants were exercised during 2018.

December 2018 Warrant Exchange

In December 2018, the Company entered into exchange agreements with several institutional investors with respect to their November 2017 Warrants and February 2018 Warrants. The Company issued to the investors 1,179 shares of Common Stock (the "Exchange Shares") in exchange for the Existing Warrants (the "Exchange"). The Exchange was made in reliance upon the exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended.

September 2018 Rights Offering

In September 2018, the Company completed the sale of 6,669 shares of its common stock, with net proceeds after expenses of approximately $7.0 million. The rights offering was made pursuant to a Registration Statement on Form S-1 that was made effective on August 3, 2018.

February 2018 Financing

In February 2018, the Company completed the sale of 606 shares of its Common Stock, 109 pre-funded warrants and the issuance of warrants to purchase 1,429 common shares (the "February 2018 Warrants") pursuant to a placement agent agreement, with net proceeds after expenses of $4.3 million. The February 2018 Warrants are exercisable one year after the anniversary date of their issuance. At December 31, 2018, the February 2018 Warrants were exercisable at $7,000 per share with 273 warrants outstanding. The Company allocated an estimated fair value of $18.3 million to the February 2018 Warrants. The Company valued the February 2018 Warrants using the following inputs: exercise price of $7,000; contractual term of six years; volatility of 122.68% and risk-free rate of approximately one percent. Due to certain price protection features in the agreement, the February 2018 Warrants were accounted for as a derivative liability at issuance and will be subsequently marked to market through the statement of operations.

In October 2018, the Company filed a registration statement on Form S-3 with the SEC, which was declared effective on December 21, 2018 and allows the Company to offer and sell, from time to time in one or more offerings, up to $100.0 million of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital at a later date. The Company has lost its Form S-3 eligibility due to the late filing of its Form 10-K for the year ended December 31, 2018. Absent prior relief from the SEC, we expect to regain S-3 eligibility on June 1, 2020.

Stock Incentive Plans

The Company's 2019 Equity Incentive Plan (the "Plan") allows for grants in the form of incentive stock options, nonqualified stock options, stock units, stock awards, stock appreciation rights, and other stock-based awards. All of the Company's officers,

directors, employees, consultants and advisors are eligible to receive grants under the Plan. The maximum number of shares reserved for issuance under the Plan is 2,142. Options to purchase shares of common stock are granted at exercise prices not less than 100% of fair value on the dates of grant. As of December 31, 2019, the Plan had approximately 502 shares available for grant.

The following is a summary of stock option activity under the Plan for the year ended December 31, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2019	—			
Granted	1,782	$ 196.70		
Exercised	—			
Cancelled/Forfeited	(142)	$ 196.70		
Outstanding at December 31, 2019	1,640	$ 196.70	9.1	$ —
Exercisable at December 31, 2019	1,502	$ 196.70	9.1	$ —

At December 31, 2019, there was approximately $25,000 of total unrecognized compensation expense related to non-vested share-based compensation awards under the plans for employee and board stock option grants. The cost is expected to be recognized over a weighted average period of 0.1 year. For the years ended December 31, 2019 and 2018, the Company recognized compensation expense $0.3 million and compensation income of $0.04 million, respectively, related to stock options granted to employees and board members.

For the year ended December 31, 2019 the Company did not recognize any restricted stock compensation expense. For the year ended December 31, 2018, the Company recognized compensation expense of approximately $0.1 million related to restricted stock granted to employees and consultants.

(in thousands)	Twelve months ended December 31, 2019	Twelve months ended December 31, 2018
Selling, general and administrative	$ 213,807	$ 120,850
Research and development	59,391	(61,867)
Total	$ 273,198	$ 58,983

Warrants

The following is a summary of warrant activity for the years ended December 31, 2019 and 2018:

	Warrants	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at January 1, 2018	20	$857,500 - $13,798,400,000	$ 4,868,205,366	4.88
Warrants issued	100,352		222	
Warrants exercised	(6,536)		1,252	
Warrants expired	(1)		13,798,400,000	
Outstanding at December 31, 2018	93,835	$7 - $7,000	$ 151	5.75
Warrants issued	1,826,579		42	
Warrants exercised	(11,285)		7	
Warrants exchanged	(82,521)		170	
Outstanding at December 31, 2019	1,826,608	$7 - $23	$ 23	4.99

(12) ***Fair Value Measurements***

The table below presents the activity within Level 3 of the fair value hierarchy for the twelve months ended December 31, 2019:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

(in thousands)	Warrant Liability
Balance at January 1, 2018	$ 560
Fair value of warrants issued	23,533
Total change in the liability included in earnings	(19,706)
Reclass from liability to equity	(4,210)
Fair value of warrants exchanged	(144)
Balance at December 31, 2018	33
Total change in the liability included in earnings	(17,498)
Reclass from liability to equity	(11)
Fair value of warrants issued	20,844
Balance at December 31, 2019	3,368

At December 31, 2018, the Company had a total of 179 February 2018 Warrants outstanding, which were surrendered pursuant to a settlement agreement entered into between the Company and the holders of the February 2018 Warrants on April 18, 2019 and final payment under the settlement was made on July 16, 2019.

The fair value of the Warrants at December 31, 2019 was determined by using option pricing models assuming the following:

	December 31, 2019	December 31, 2018
Expected life (in years)	4.6	1.1 - 5.1
Expected volatility	207.5%	145.7% - 265.3%
Risk-free interest rates	1.7%	2.5% - 2.6%

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2019 and 2018, aggregated by the level in the fair value hierarchy within which those measurements fall.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

	Assets and Liabilities Measured at Fair Value on a Recurring Basis							
	Level 1		Level 2		Level 3		Balance at December 31,	
(in thousands)	2019	2018	2019	2018	2019	2018	2019	2018
Liabilities								
Derivative instrument liabilities	$ —	$ —	$ —	$ —	$ 3,368	$ 33	$ 3,368	$ 33

For the twelve months ended December 31, 2019 and 2018 there were no transfers in or out of Level 1, 2 or 3 inputs.

(13) **Commitments**

Financing Lease

In January 2019, the Company entered into an amendment (the "Park Road Lease Amendment") to a lease agreement entered into in October 2018 (the "Park Road Lease") for approximately 6,000 square feet of space located at 95-97 Park Road in Queensbury, New York. Under the terms of the Park Road Lease Amendment, the original two year term which began on October 31, 2018 was extended through November 2020 and provides for total annual base rent of $50,000 per year.

Operating Leases

In September 2018, the Company entered into an amendment (the "1633 Sublease Amendment") to a sub-lease agreement executed in March 2016 (the "1633 Sublease) for approximately 6,877 square feet of office space at 1633 Broadway, New York, NY. The term began in April 2016 and under the terms of the 1633 Sublease Amendment is extended through February 2021 and provides for total annual base rent of $0.5 million.

In August 2011, Delcath Systems Ltd. entered into an agreement of lease for an office and manufacturing facility located in the city of Galway, Ireland. This facility is approximately 19,200 square feet and is intended to be the location of Delcath's European headquarters. The Lease is for a term of ten years, commencing August, 2011. The Lease provides for fixed annual lease amounts payable in advance in equal quarterly installments. The remaining annual lease amount is $0.2 million. Delcath Systems Ltd. is also required to pay for customary building operating expenses. Delcath Systems Ltd.'s payment obligations and performance of the Lease are guaranteed by Delcath. The Company has sub-leased a portion of this facility.

Future minimum lease payments, net of receipts due under the terms of subleases, under all operating leases at December 31, 2019 are as follows:

(in thousands)	Future Lease Payments
2020	635
2021	79
	$ 714

For the years ended December 31, 2019 and 2018 rent expense, net of receipts under the terms of subleases, totaled approximately $0.5 million and $0.6 million, respectively.

Letters of Credit

Under the terms of a sub-lease agreement for office space at 1633 Broadway, New York, NY, the Company is required to maintain a letter of credit in the amount of $0.1 million which will expire with the sublease in February 2021.

(14) Income Taxes

There is no income tax expense recognized for the years ended December 31, 2019 and 2018, respectively.

Loss before taxes consists of:

(in thousands)	December 31, 2019	December 31, 2018
Domestic	$ (4,882)	$ (12,961)
Foreign	(3,997)	(6,261)
Income (loss) before taxes	$ (8,879)	$ (19,222)

The provision for income taxes differs from the amount computed by applying the statutory rate as follows:

(in thousands)	December 31, 2019	December 31, 2018
Income taxes using U.S federal statutory rate	$ (1,865)	$ (4,037)
Tax Cuts and Jobs Act	—	—
Nondeductible interest	994	2,273
Loss on extinguishment of debt	361	236
Loss of tax benefit of federal net operating loss carryforwards	—	(588)
Loss of tax benefit of state net operating loss carryforwards	1,477	1,040
Loss of tax benefit of federal tax credit carryforwards	324	495
Amortization of gain on IP migration	—	—
State income taxes, net of federal benefit	(1,461)	(2,355)
Foreign rate differential	664	1,166
Valuation allowance	3,512	6,323
Derivative charge	(3,674)	(4,138)
Stock option exercises and cancellations	—	215
Research and development costs	(316)	(636)
Other	(16)	6
	$ —	$ —

Significant components of the Company's deferred tax assets are as follows:

(in thousands)	December 31, 2019	December 31, 2018
Deferred tax assets:		
Equity compensation	$ 84	$ —
Accrued liabilities	—	519
Research tax credits	135	161
Lease obligation	206	
Other	72	60
Net operating losses	14,502	10,624
Total deferred tax assets	$ 14,999	$ 11,364
Deferred tax liabilities:		
Beneficial conversion feature	—	—
Right of use asset	206	—
Other	—	—
Total deferred tax liabilities	206	—
Valuation allowance	14,793	11,364
Net deferred tax assets	$ —	$ —

As of December 31, 2019 and 2018 the Company had net operating loss carryforwards for U.S. federal income tax purposes of approximately $246.3 million and $230.0 million, respectively. A significant portion of the federal amount is subject to an annual limitation as low as $27,500 as a result of changes in the Company's ownership in May 2003, November 2016, and multiple dates throughout 2017, 2018 and 2019, as defined by Federal Internal Revenue Code Section 382 and the related income tax regulations. As a result of the limitations caused by the May 2003, November 2016 and multiple 2017, 2018 and 2019 ownership changes, approximately $207.0 million of the total net operating loss carryforwards is expected to expire unutilized and will be unavailable to offset future federal taxable income. Approximately $39.3 million of net operating loss carryforwards remains available to offset future federal taxable income, of which $1.7 million will expire between 2020 and 2037 and $37.6 million will have an unlimited carryforward period as a result of the Tax Cuts and Jobs Act.

In addition, the Company's state net operating losses are also subject to annual limitations that generally follow the federal Section 382 provisions (with the exception of Connecticut), adjusted for each state's respective income apportionment percentages. As of December 31, 2019 and 2018, the Company had net operating loss carryforwards for state and city income tax purposes between approximately $27.3 million and $180.6 million and between approximately $27.3 million and $167.3 million, respectively, which expire through 2039. As a result of the 382 limitations, approximately $169.4 million and $153.7 million of New York State and New York City net operating losses are expected to expire unutilized and will be unavailable to offset future taxable income. Approximately $11.2 million and $11.2 million of net operating loss carryforwards, respectively, will be available to offset future state and city taxable income. As of December 31, 2019 and 2018 the Company had a net operating loss carryforward for foreign income tax purposes of $26.1 million and $25.2 million, respectively, which have indefinite carryforward periods. As of December 31, 2019 and 2018, the Company had federal research and development tax credit carryforwards of approximately $5.3 million and $5.0 million respectively, which expire through 2039. As a result of the section 382 limitations, all but $0.1 million of the tax credit carryforwards is expected to expire unutilized.

Management has established a 100% valuation allowance against the deferred tax assets as management does not believe it is more likely than not that these assets will be realized. The Company's valuation allowance increased by approximately $3.4 million and increased by $5.4 million in 2019 and 2018, respectively. The change in valuation is as follows:

(in thousands)	December 31, 2019	December 31, 2018
Beginning balance	$ 11,364	$ 5,972
Charged to costs and expenses	3,512	6,323
Charged to additional paid-in capital	—	—
Charged to retained earnings	—	(834)
Charged to other comprehensive income	(83)	(97)
Ending balance	$ 14,793	$ 11,364

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act (the "Act"). The Act, which is also commonly referred to as "U.S. tax reform", significantly changes U.S. corporate income tax laws by, among other provisions, reducing the maximum U.S. corporate income tax rate from 35% to 21% starting in 2018. During the year ended December 31, 2017, the Company reduced deferred tax assets by a provisional amount of $143,500, offset by a corresponding reduction to its valuation allowance, as a result of the re-measurement of deferred tax assets and liabilities from its 34% effective rate under existing law to the new lower statutory rate of 21%. The Company finalized its accounting of the effects of tax reform in 2018, which resulted in insignificant adjustments.

The Act also requires a mandatory one-time inclusion of the deferred foreign income of controlled foreign corporations. The one-time transition tax is based on Delcath's total post-1986 earnings and profits (E&P) for which the Company has previously deferred from U.S. income taxes. During the year ended December 31, 2017, the Company's reasonable estimate resulted in no provisional amount for the one-time transition tax liability, as the Company's international subsidiaries are expected to have a cumulative deficit in E&P. As the Company's international subsidiaries have a cumulative deficit in earnings and profits, the Company did not anticipate being affected by the mandatory inclusion provisions of the Act. The Company finalized its calculation of the total post-1986 foreign E&P (including deficits) for these foreign subsidiaries during 2018 and was not impacted by the mandatory inclusion provisions of the Act.

On December 22, 2017, Staff Accounting Bulletin 118 was issued due to the complexities involved in accounting for the recently enacted Act. SAB 118 requires the Company to include in its financial statements a reasonable estimate of the impact of the Act on earnings to the extent such estimate has been determined. Accordingly, the U.S. provision for income tax for

December 31, 2017 was based on the reasonable estimate guidance provided by SAB 118. The Company finalized the impact from the Act during 2018 and recorded insignificant adjustments.

The Company complies with the provisions of ASC 740-10, Income Taxes, in accounting for its uncertain tax positions. ASC 740-10 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The Company has determined that the Company has no significant uncertain tax positions requiring recognition under ASC 740-10 and therefore has not included a tabular rollforward of unrecognized tax benefits. As there are no uncertain tax positions recognized, interest and penalties have not been accrued.

The Company is subject to income tax in the U.S., as well as various state and international jurisdictions. The Company has not been audited by any state tax authorities in connection with income taxes. The Company has not been audited by international tax authorities or any states in connection with income taxes. The Company's New York State tax returns have been subject to annual desk reviews which have resulted in insignificant adjustments to the related franchise tax liabilities and credits. The Company is no longer subject to federal and state examination for tax years ending prior to December 31, 2016; tax years ending December 31, 2016 through December 31, 2019 remain open to examination. The Republic of Ireland is the Company's only significant foreign jurisdiction. The Company is no longer subject to Ireland tax examination for tax years ending prior to December 31, 2015 (as Ireland has not initiated an audit of 2014 as of December 31, 2019); tax years ending December 31, 2014 through December 31, 2018 remain open to examination. However, the Company's tax years December 31, 1998 through December 31, 2019 generally remain open to adjustment for all federal, state and foreign tax matters until its net operating loss and tax credit carryforwards are utilized or expire prior to utilization, and the applicable statutes of limitation have expired in the utilization year. The federal and state tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations.

Delcath recognizes interest accrued related to unrecognized tax benefits and penalties, if incurred, as a component of income tax expense.

(15) Subsequent Events

Since January 1, 2020, the Company has issued 2,915 shares pursuant to conversions of Series E and Series E-1 Convertible Preferred Stock.

In May 2018, the Company received a Demand Letter from a vendor for an outstanding balance owed at that time of $2.1 million. At that time, the Company agreed with the vendor on a payment plan for the balance owed. Subsequent to December 31, 2019, the vendor issued a notice of default relating to the Demand Letter. As a result, the Company paid $0.9 million, representing the remaining balance owed.

In February 2020, we issued 2,717 shares of restricted common stock in relation to certain advisory services received by us. In connection with the foregoing, we relied upon the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, for transactions not involving a public offering.

In connection with our proposed public offering (the "Proposed Offering") of our securities pursuant to our registration statement on Form S-1 (File No. 333-235904), and the potential listing of the Company's common stock, par value $0.01 per share (the "Common Stock") on the Nasdaq Capital Market in connection therewith, on March 11, 2020, the Company entered into a support and conversion agreement (the "Support and Conversion Agreement") with Rosalind Master Fund L.P. and Rosalind Opportunities Fund I L.P. (collectively, "Rosalind") and our executive officers. The Support and Conversion Agreement provides that, among other things, the executive officers have agreed to receive payment of the net after-tax amount of their 2019 annual incentive bonuses aggregating $221,000 in unregistered shares of Common Stock, valued at the public offering price of the securities sold in the Proposed Offering, upon the consummation of the Proposed Offering. In addition, following the consummation of the Proposed Offering, (i) Rosalind has agreed that from time to time the Company may require them to convert all or a portion of their 8% senior secured promissory notes in the aggregate principal amount of $2 million (the "Notes") into shares of the Company's Series E convertible preferred stock (the "Series E Preferred Stock") and Series E

warrants at the contractual conversion price of $1,500 per share of Series E Preferred Stock in certain circumstances described below (a "Rosalind Conversion"), and (ii) the Company's executive officers have agreed to receive payment of the net after-tax amounts of back pay and deferred bonuses aggregating $765,000 in unregistered shares of Common Stock (an "Equitization Transaction," and together with a Rosalind Conversion, an "Equity Infusion"). The shares of Common Stock issuable in an Equitization Transaction would have a value equal to the greater of (x) the last reported sale price per share as of the trading day immediately preceding the Equity Infusion Date (as defined below) and (y) the volume-weighted average price of the Common Stock for the five trading days immediately preceding the Equity Infusion Date.

The recent outbreak of a novel strain of coronavirus (COVID-19) has had an impact on our ability to monitor data at our clinical trial sites and is likely to cause a decline in product revenue for the forseeable future as many hospitals are prioritizing the treatment of patients diagnosed with COVID-19. This situation is rapidly changing and additional impacts to the business may arise that we are not aware of currently. The ultimate impact of the pandemic on the Company's results of operations, financial position, liquidity or capital resources cannot be reasonably estimated at this time.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of its Chief Executive Officer, evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) of the Exchange Act. Based on that evaluation, Delcath's Chief Executive Officer concluded that the Company's disclosure controls and procedures as of December 31, 2019 (the end of the period covered by this Annual Report on Form 10-K), have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by the Company in its reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Chief Executive Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Delcath's management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Delcath's management assessed the effectiveness of its internal control over financial reporting as of December 31, 2019. In making this assessment, it used the criteria set forth in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on such assessment, management has concluded that, as of December 31, 2019, the Company's internal control over financial reporting was effective based on those criteria.

Changes in Internal Control Over Financial Reporting

There were no changes to the Company's internal control over financial reporting that occurred during the fourth fiscal quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, its internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

Information About Directors. The following table sets forth certain information about our directors.

Name	Age	Position with Delcath	Director Since
Elizabeth Czerepak	64	Director	2020
William D. Rueckert	67	Director	2014
Roger G. Stoll, Ph.D.	77	Chairman	2008
John Sylvester	56	Director	2019
Jennifer K. Simpson, Ph.D.	51	Director	2015
Marco Taglietti, M.D.	60	Director	2014

Elizabeth Czerepak was appointed as a Director in February 2020. Ms. Czerepak served as Chief Financial Officer and Chief Business Officer at Genevant Sciences, Inc., a development stage mRNA start-up based in Cambridge, MA, from May 2018 until January 2020. From 2015 until 2018, she served as Chief Financial Officer and Executive Vice President, Corporate Development at Altimmune, Inc. (NASDAQ:ALT), a clinical stage immunotherapeutics biotechnology company. She served as Chief Financial Officer and Chief Business Officer of Isarna Therapeutics Inc., which developed selective TGFb inhibitors to fight cancer and to treat ophthalmic and fibrotic diseases, from 2014 to 2015. Prior to that she served as Chief Financial Officer, Secretary, Principal Accounting Officer and Head of Human Resources at Cancer Genetics, Inc. (NASDAQ:CGIX), a company that develops, commercializes and provides molecular and biomarker-based tests, from 2011 until 2014. From 2000 to 2009, she served as a Managing Director at JPMorgan Chase & Co. and Bear Stearns & Co., and a General Partner at Bear Stearns Health Innoventures L.P., a venture capital fund. From 1982 to 2000, she served in senior and executive level position at BASF (Knoll) Pharma, Hoffmann-La Roche, Inc. and Merck & Co., Inc. (NASDAQ:MRK). The Nominating Committee considered Ms. Czerepak's experience and qualifications, in addition to her relevant executive management and operational pharmaceutical experience, as well as the overall composition of the Board, in making the determination that Ms. Czerepak should serve as director of Delcath.

William D. Rueckert was appointed as a Director in December 2014. Mr. Rueckert has served on many public and private corporate boards in both the life science and banking industries. He is currently President of Oyster Management Group, LLC, an investment partnership specializing in community banking. He served on the board of Novogen Ltd. (now Kazia Therapeutics Ltd., NASDAQ:KZIA), a biotechnology company based in Sydney, Australia from 2007 until 2012, acted as Chairman from 2010 until 2012, and as acting CEO led the restructuring of the company, spinning off its major subsidiary, Marshall Edwards, Inc. (now MEI Pharma, Inc. NASDAQ:MEIP). Until 2019, he was a director of MEI Pharma, Inc. (NASDAQ), a San Diego based company that is developing novel oncology therapies. Until its sale to H. Lundbeck A/S, he was a director of Chelsea Therapeutics International, Ltd. whose drug candidate, Northera, was approved by the FDA in 2014. He has also served on the boards of several banks including Westport Bank and Trust, Lafayette American Bank and Hudson United Bank. He currently serves on the board of Fairfield County Bank, a mutually owned, community bank based in Ridgefield, CT. Among his civic associations, Mr. Rueckert is a Director and President of the Cleveland H. Dodge Foundation, Chairman of the Board of Trustees of Teachers College, Columbia University, Chairman of the Board of Trustees of the YMCA Retirement Fund, a Trustee of International House, an Emeritus Director of the YMCA of Greater New York, a Trustee of the American University of Beirut and a Director of Wave Hill, Inc. He earned a BA in Spanish in 1977 from the University of New Hampshire. The Nominating Committee considered Mr. Rueckert's experience and qualifications, in addition to his relevant executive management and operational pharmaceutical experience, as well as the overall composition of the Board, in making the determination that Mr. Rueckert should serve as director of Delcath.

Roger G. Stoll, PhD. was appointed as a Director in December 2008. He became Executive Chairman in September 2014 and has served as Chairman of the Board since October 2015. From 2002 to 2008 he served as Chairman and Chief Executive Officer of Cortex Pharmaceuticals, Inc. (now RespireRx Pharmaceuticals Inc.). In August of 2008 he was appointed Executive Chairman of the board of directors of Cortex and retired in 2012. From 2001 to 2002 he was a consultant to several east coast venture capital firms and startup ventures. From 1998 to 2001, he was Executive Vice President of Fresenius Medical Care-North America, in charge of the dialysis products division and the diagnostic business units, which included hemodialysis machines, dialysis filters, dialysate solutions, and attendant devices used in the dialysis procedure. From 1991 to 1998, Dr. Stoll was Chief Executive of Ohmeda, a global leader in anesthetic agents, critical care drugs and related operating room devices with sales of $1 billion annually. From 1986 to 1991, Dr. Stoll held several positions of increasing responsibility at Bayer, AG including, Chief Administrative Office, President of Consumer Healthcare business unit, and Executive Vice-President and General Manager for its worldwide Diagnostic Business Group which included the acquisition of The Tecnicon Company and globally integrating the Bayer and Techincon business units. This resulted in a global diagnostic business in excess of $1 billion in sales annually. Prior to that he worked for American Hospital Supply Corporation, where he rose from Director of Clinical Pharmacology to President of the American Critical Care drug division of

AHSC. He began his pharmaceutical career at the Upjohn Company working in drug metabolism and pharmacokinetic studies in a clinical development unit in 1972. Dr. Stoll obtained his BS in Pharmacy degree at Ferris State University, his PhD in Biopharmaceutics and drug metabolism at the University of Connecticut and was a post-doctoral fellow for two years at the University of Michigan. He served on the board of Agensys, Inc from 2003 until its sale to Astellas in late 2007. Dr. Stoll served on the board of Questcor Pharmaceuticals from 1999 to 2004, and Chelsea Therapeutics until it was acquired in 2008 by Lundbeck A/S. Dr. Stoll also serves on the University of Connecticut School of Pharmacy Advisory Board. The Nominating Committee considered Dr. Stoll's experience and qualifications in both pharmaceuticals and medical devices and equipment in addition to his relevant executive management experience, as well as the overall composition of the Board, in making the determination that Dr. Stoll should serve as a director of Delcath.

John R. Sylvester was appointed as a Director in July 2019. He served as Chief Commercial Officer of BTG plc from 2011 to 2019 and had roles leading both their Interventional Oncology and Interventional Vascular businesses as well as a period as Chief Development Officer accountable for Strategy, M&A and Market access since 2015. Prior to BTG, Mr. Sylvester was Managing Director of Biocompatibles plc, building their Interventional Oncology business which led to a successful exit to BTG for £166.0 million. Mr. Sylvester joined Biocompatibles following a period as the Vice President of Marketing for Baxter Healthcare's $750.0 million European Medication Delivery business based in Brussels then Zurich accountable for six strategic business units incorporating drugs, devices and drug device combinations. Before this, Mr. Sylvester held a number of senior commercial roles in the industrial sector. Immediately prior to Baxter Healthcare, he was the General Manager of a Minerals company with $4.0 billion of assets on three continents, $500.0 million of sales and 1,500 employees. Mr. Sylvester graduated with joint honors in Biochemistry and Applied Molecular Biology from the University of Manchester Institute of Science and Technology (U.M.I.S.T.). The Nominating Committee considered Mr. Sylvester's experience and qualifications in pharmaceuticals and his relevant executive management experience, as well as the overall composition of the Board, in making the determination that Mr. Sylvester should serve as a director of Delcath.

Dr. Marco Taglietti, M.D. was appointed as a Director in December 2014. Dr. Taglietti currently serves as President and CEO and is on the Board of Directors of SCYNEXIS, Inc. (NASDAQ:SCYX), a pharmaceutical company committed to the discovery, development and commercialization of novel anti-infectives. Prior to its acquisition in February 2014, Dr. Taglietti served as Executive Vice President, Research and Development, and Chief Medical Officer of Forest Laboratories. He also served as President of the Forest Research Institute. Prior to joining Forest Laboratoriess in 2007, Dr. Taglietti held the position of Senior Vice President, Head of Global Research and Development, at Stiefel Laboratories, Inc. for three years. He joined Stiefel after 12 years at Schering-Plough Corporation (now Merck & Co., Inc.) where he last held the position of Vice President, Worldwide Clinical Research for Anti-Infectives, Oncology, CNS, Endocrinology and Dermatology. Dr. Taglietti began his career at Marion Merrell Dow Research Institute. Dr. Taglietti served on the Board of Directors and as a member of the Compensation Committee of NephroGenex, Inc., a pharmaceutical company focused on the development of therapeutics to treat kidney disease, from 2014 to 2016. He received his medical degree and board certifications from the University of Pavia in Italy. The Nominating Committee considered Dr. Taglietti's experience and qualifications, in addition to his relevant executive management and operational pharmaceutical experience, as well as the overall composition of the Board, in making the determination that Dr. Taglietti should serve as director of Delcath.

Simon Pedder resigned as a member of the Board of Directors of the Company effective April 10, 2019. Mr. Pedder's decision to resign was not the result of any disagreement with the Company on any matter relating to its operations, policies or practices.

In addition, information concerning Jennifer K. Simpson, one of our Directors and our President and Chief Executive Officer, is provided under "—Information About Our Executive Officers"

Information About our Executive Officers

The following table provides information concerning the current executive officers of Delcath:

Name	Age	Office Currently Held
Jennifer K. Simpson	51	President and Chief Executive Officer
Barbra C. Keck	42	Chief Financial Officer and Secretary
John Purpura	58	Executive Vice President, Global Head of Operations

The following is a brief description of the business experience of our executive officers:

Jennifer K. Simpson was appointed as a Director in October 2015. Dr. Simpson joined Delcath as Executive Vice President, Global Marketing in March 2012 and was promoted to Executive Vice President, Global Head of Business Operations in April 2013 and Interim Co-President and Co-Chief Executive Officer, Executive Vice President, Global Head of Business Operations in September 2013. In September 2014, Dr. Simpson was named Interim President and Chief Executive Officer and named President and Chief

Executive Officer in May 2015. From May 2011 to March 2012, Dr. Simpson served as the Vice President, Global Marketing, Oncology Brand Lead at ImClone Systems, Inc. (a wholly owned subsidiary of Eli Lilly and Company (NYSE:LLY)), where she was responsible for all product commercialization activities and launch preparation for one of the late-stage assets. From June 2009 to May 2011, Dr. Simpson served as the Vice President, Product Champion and from 2008 to 2009 as the Associate Vice President, Product Champion for ImClone's product Ramucirumab. From 2006 to 2008, Dr. Simpson served as Product Director, Oncology Therapeutics Marketing at Ortho Biotech (now Janssen Biotech), a Pennsylvania-based biotech company that focuses on innovative solutions in immunology, oncology and nephrology. Earlier in her career, Dr. Simpson spent over a decade as a hematology/oncology nurse practitioner and educator. Dr. Simpson has served on the Board of Directors and Nominating and Corporate Governance Committee of Eagle Pharmaceuticals, Inc. (NASDAQ:EGRX) since 2019. Dr. Simpson earned a Ph.D. in Epidemiology from the University of Pittsburgh, an M.S. in Nursing from the University of Rochester, and a B.S. in Nursing from the State University of New York at Buffalo. The Nominating Committee considered Dr. Simpson's experience and qualifications in pharmaceuticals and her relevant executive management experience, as well as the overall composition of the Board, in making the determination that Dr. Simpson should serve as a director of Delcath.

Barbra C. Keck joined Delcath as Controller in January 2009, was promoted to Vice President in October 2009, to Senior Vice President in March 2015 and to Chief Financial Officer in February 2017. Prior to joining Delcath, she was an audit assistant with Deloitte & Touche, LLP from August 2008 to December 2008. From June 2006 to August 2008, Ms. Keck was the Assistant to the Vice President and Dean of Baruch College, Zicklin School of Business, and from September 2005 to May 2006 she was the Donor Relations and Communications Manager for Young Audiences New York. From 2002 to 2005, Ms. Keck was the Manager, UD Arts Series at the University of Dayton, where she also served as the Manager, Arts and Cultural Events from 1999 to 2002. Between those positions, from 2002 to 2003, she was the Director of Teacher Programs at the Muse Machine. Ms. Keck served as the General Manager of Dayton Bach Society and the Manager of UD Arts Series from 1999 to 2002. She earned her M.B.A. in Accountancy from Baruch College and Bachelor of Music in Music Education from the University of Dayton.

John Purpura joined Delcath as Executive Vice President, Regulatory Affairs and Quality Assurance in November 2009 and was promoted to Executive Vice President, Global Head of Operations on July 19, 2016. Prior to joining Delcath, he was with Bracco Diagnostics (formerly E-Z-EM,Inc.) as Vice President and then Executive Director of International Regulatory Affairs from 2007 to 2008 and Head of Regulatory Affairs for North America and Latin America from 2008 to 2009. Prior to E-Z-EM, Inc., Mr. Purpura had an 11-year career with Sanofi-Aventis (NASDAQ:SNY), ultimately serving as Associate Vice President for Regulatory CMC from 2005 to 2007. From 1985 to 1995, he had various quality and regulatory management roles with Bolar Pharmaceuticals, Luitpold Pharmaceuticals and Eon Labs Manufacturing. He earned his M.S. in Management & Policy and B.S. degrees in Chemistry and Biology at the State University of New York at Stony Brook.

Corporate Governance

Board of Directors. We have currently have six directors serving on the Board of Directors. The Board of Directors oversees the business affairs of the Company and monitors the performance of management. In accordance with our corporate governance principles, our Board does not involve itself in day-to-day operations. The directors keep themselves informed through discussions with the Chairman of the Board, Roger G. Stoll, Jennifer K. Simpson, in her capacity as Director and Chief Executive Officer, or CEO, and other key executives, and by reading the reports and other materials that management sends them and by participating in Board and committee meetings. Our directors hold office until their successors have been elected and qualified unless the director resigns or is removed or by reason of death or other cause is unable to serve in the capacity of director.

Board Independence. The Board has determined that five of our six directors (each of Elizabeth Czerepak, William D. Rueckert, Roger G. Stoll, John R. Sylvester and Marco Taglietti) are "independent" directors within the meaning of the NASDAQ listing rules.

Attendance. The Board of Directors met 19 times in 2019 (including regularly scheduled and special meetings). During 2019, each director attended at least 75% of the aggregate of: (i) the total number of meetings of the Board (held during the period for which he or she served as a director) and (ii) the total number of meetings held by all committees of the Board of Directors on which he or she served (held during the period that he or she served).

Board Leadership Structure. Roger G. Stoll, Ph.D. was appointed Executive Chairman effective September 2014 and designated Chairman in connection with the appointment of Dr. Simpson as director effective October 2015. Dr. Stoll has been a member of the Board of Directors since 2008.

It is our policy to separate the Chairman and Chief Executive Officer roles. We believe this structure is appropriate for our company because it allows our President and CEO to concentrate on our day-to-day operations, while providing for effective oversight by the Chairman, who is involved in strategic and key matters, such as business strategy, major transactions and the broader business of our company. For a company like ours that is focused on the development, approval and commercialization of a specialized product in an

extremely technical, highly regulated and intensely competitive industry, we believe our President and CEO is in the best position to lead our management team, in part because of the depth of her experience in conducting clinical trials in oncology, and to respond to the current pressures and needs of a company in the stage of growth and development of our company, with assistance from our Chairman who also focuses the Board's attention on the broader issues of corporate business strategy and corporate governance. We believe that splitting the roles between Chairman, on the one hand, and President and CEO, on the other hand, minimizes any potential conflicts that may result from combining the roles of CEO, President and Chairman, and maximizes the effectiveness of our management and governance processes to the benefit of our stockholders. Our President and CEO and Chairman regularly consult with each other as part of this structure.

Board's Role in Risk Oversight. The Board as a whole is responsible for risk oversight, with reviews in certain areas being conducted by the relevant Board committees. Each of the Board's committees oversees the management of risks associated with their respective areas of responsibility. In performing this oversight function, the committees are assisted by management which provides visibility about the identification, assessment and monitoring of potential risks and management's strategy to mitigate such risks. Key members of management responsible for a particular area report directly to the Board committee charged with oversight of the associated function and, if the circumstances require, the whole Board. The Board committees review various risk exposures with the full Board and otherwise keep the full Board abreast of the committees' risk oversight activities throughout the year, as necessary or appropriate.

Risk Assessment of Compensation Programs. Our Compensation and Stock Option Committee annually evaluates whether our compensation programs encourage excessive risk-taking by employees at the expense of long-term value of our company. Based upon its assessment, including a review of the overall annual award limitations and individual annual limitations in our stock incentive plans and the Compensation Committee's role in the consideration and approval of certain awards, the Compensation and Stock Option Committee does not believe that our compensation programs encourage excessive or inappropriate risk-taking, motivate imprudent risk-taking or create risks that are reasonably likely to have a material adverse effect on our company.

Board Committees. Our Board has three standing committees: an Audit Committee, a Compensation and Stock Option Committee and a Nominating and Corporate Governance Committee. No individual director is the chairman of more than one committee.

Audit Committee. The Audit Committee provides assistance to the Board in fulfilling its oversight responsibilities with respect to our financial statements, our system of internal accounting and financial controls and the independent audit of our financial statements. Functions of the Audit Committee include:

- the selection, evaluation and, where appropriate, replacement of our outside auditors;
- an annual review and evaluation of the qualifications, performance and independence of our outside auditors;
- the approval of all auditing services and permitted non-audit services provided by our outside auditors;
- the review of the adequacy and effectiveness of our accounting and internal controls over financial reporting; and
- the review and discussion with management and with our outside auditors of the Company's financial statements to be filed with the Commission.

The current members of the Audit Committee are William D. Rueckert (Chair), Elizabeth Czerepak and Roger G. Stoll. The Board has determined that each of William D. Rueckert, Elizabeth Czerepak and Roger G. Stoll qualifies as an "audit committee financial expert" as defined by SEC rules. During 2019, the Audit Committee met four times. Each member of the Audit Committee is "independent" within the meaning of the NASDAQ listing rules and otherwise meets the financial statement proficiency requirements of the NASDAQ listing rules. The Audit Committee has a written charter, which is available on our website; go to www.delcath.com, click on "Investors," then "Corporate Governance."

Compensation and Stock Option Committee. The Compensation and Stock Option Committee, or the Compensation Committee, assists the Board of Directors in the discharge of the Board's responsibilities with respect to the compensation of our directors, executive officers, and other key employees and consultants. The Compensation Committee establishes our overall compensation philosophy and is authorized to approve the compensation payable to our executive officers, including our named executive officers, and other key employees, including all perquisites, equity incentive awards, cash bonuses, and severance packages. The Compensation Committee also administers certain of our employee benefit plans, including its equity incentive plans, and is responsible for assessing the independence of compensation consultants and legal advisors. The Compensation Committee has concluded that Lowenstein Sandler LLP, outside legal counsel to the Compensation Committee and the Company qualified as independent. The Compensation Committee exercises sole power to retain compensation consultants and advisors and to determine the scope of the associated engagements. The current members of the Compensation and Stock Option Committee are Marco Taglietti (Chair) and William D. Rueckert, and Roger G. Stoll, each of whom is "independent" within the meaning of NASDAQ listing rules. During 2019, the Compensation and Stock Option Committee met one time. The Compensation and Stock Option Committee has a written charter, which is available on our website; go to www.delcath.com, click on "Investors," then "Corporate Governance."

Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee, or the Nominating Committee, is responsible for identifying individuals qualified to become Board members, and recommends to the Board the director nominees to be proposed by the Board for election by the stockholders (as well as any director nominees to be appointed by the Board to fill interim vacancies). The Nominating Committee also recommends the directors to be selected for membership on each Board committee.

The Nominating Committee is also responsible for developing and recommending to the Board appropriate corporate governance guidelines and policies, and for leading the Board in its annual review of the Board's performance.

The current members of the Nominating Committee are Roger G. Stoll (Chairman), William D. Rueckert and John Sylvester, each of whom is "independent," within the meaning of NASDAQ listing rules. During 2019, the Nominating Committee met two times. The Nominating Committee has a written charter, which is available on our website; go to www.delcath.com, click on "Investors," then "Corporate Governance."

The Nominating Committee, with, when it deems it necessary, the assistance of a third-party search firm, identifies candidates for director nominees. In considering candidates for the Board, the Nominating Committee considers each candidate's credentials as a whole, including, but not necessarily limited to, outstanding achievement in a candidate's personal career, broad and relevant experience, integrity, sound and independent judgment, experience and knowledge of the business environment and markets in which we operate, business acumen, and willingness and ability to devote adequate time to Board duties. The Nominating Committee considers the diversity of its members in the context of the Board as a whole, including the personal characteristics, experience and background of directors and nominees to facilitate Board deliberations that reflect a broad range of perspectives.

Recommendations by Stockholders of Director Nominees. The Nominating Committee will consider any recommendation by a stockholder of a candidate for nomination as a director. If a stockholder wants to recommend a director candidate for consideration by the Nominating Committee, the stockholder should submit the name of the proposed nominee, together with the reasons why the stockholder believes the election of the candidate would be beneficial to our company and our stockholders and the information about the nominee that would be required in a proxy statement requesting proxies to vote in favor of the candidate. The stockholder's submission must be accompanied by the written consent of the proposed nominee to being nominated by the Board and the candidate's agreement to serve if nominated and elected. Any such submission should be directed to the Nominating Committee at our principal office, 1633 Broadway, Suite 22C, New York, New York 10019. If a stockholder intends to nominate a person for election to the Board of Directors at an annual meeting, the stockholder must provide us with written notice of his or her intention no later than the deadline for receiving a stockholder proposal for inclusion in our proxy statement for such meeting and must otherwise comply with our amended and restated certificate of incorporation. Copies of any recommendation received in accordance with these procedures will be distributed to each member of the Nominating Committee. One or more members of the Nominating Committee may contact the proposed candidate to request additional information.

Stockholder Communications with the Board of Directors. Any stockholder wishing to communicate with the Board or with any specified director should address his or her communication to the Board of Directors or to the particular director(s) in care of the Corporate Secretary, Delcath Systems, Inc., 1633 Broadway, Suite 22C, New York, New York 10019. All such written communication, other than items determined by our legal counsel to be inappropriate for submission to the intended recipient(s), will be submitted to the Board or to the particular director(s). Any stockholder communication not so delivered, will be made available upon request to any director. Examples of stockholder communications that would be considered inappropriate for submission include, without limitation, customer complaints, business solicitations, product promotions, job inquiries, junk mail and mass mailings, as well as material that is unduly hostile, threatening, illegal or similarly unsuitable.

Compensation Committee Interlocks and Insider Participation. During 2019, Marco Taglietti, Roger G. Stoll and William D. Rueckert served as members of our Compensation and Stock Option Committee. None of the current members or members serving during 2019 of the Compensation and Stock Option Committee is a current or former officer or employee of our company at the time of their service on the Compensation and Stock Option Committee, nor did any Compensation and Stock Option Committee member engage in any "related person" transaction that would be required to be disclosed under Item 404 of Regulation S-K. During 2019, none of our executive officers served on the compensation committee (or equivalent) or on the board of directors of another entity whose executive officers served on the Compensation and Stock Option Committee or our Board of Directors.

Code of Ethics. We maintain a Code of Business Conduct and Ethics (the "Code") that applies to all employees, including our principal executive officer, principal financial officer, principal accounting officer, controller and persons performing similar functions, and including our independent directors, who are not our employees, with regard to their company-related activities. The Code incorporates guidelines designed to deter wrongdoing and to promote honest and ethical conduct and compliance with applicable laws, rules and regulations. The Code also incorporates our expectations of our employees that enable us to provide accurate and timely disclosure in our filings with the SEC and other public communications. In addition, the Code incorporates guidelines

pertaining to topics such as complying with applicable laws, rules, and regulations; insider trading; reporting Code violations; and maintaining accountability for adherence to the Code. The full text of our Code is published on our website at http://delcath.com/investors/governance. We intend to disclose future amendments to certain provisions of our Code, or waivers of such provisions granted to our principal executive officer, principal financial officer or principal accounting officer and persons performing similar functions on our website.

REPORT OF THE AUDIT COMMITTEE

The Audit Committee reviewed and discussed the Company's audited financial statements for the fiscal year ended December 31, 2019, with management and Marcum LLP, the Company's independent registered public accounting firm for the fiscal year ended December 31, 2019. The Audit Committee also discussed with Marcum LLP the matters required to be discussed by the Statement on Auditing Standards No. 16, as amended, as adopted by the Public Company Accounting Oversight Board in Rule 3200T regarding "Communication with Audit Committees." The Audit Committee has received and reviewed the written disclosures and the letter from Marcum LLP required by applicable requirements of the Public Company Accounting Oversight Board regarding Marcum LLP's communications with the Audit Committee concerning independence, and has discussed with Marcum LLP its independence from the Company.

Based on the review and discussions referred to above, the Audit Committee recommended to the Board of Directors that the Company's audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, for filing with the SEC.

Submitted by the Audit Committee of the Board of Directors,
William Rueckert (Chair)
March 25, 2020

DELINQUENT SECTION 16(A) REPORTS

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and officers, and persons who are beneficial owners of more than 10% of our common stock to file with the SEC reports of holdings and changes in beneficial ownership of Delcath's equity securities. Based on a review of copies of reports furnished to Delcath or written representations that no reports were required, with the exception of the Form 4s filed on July 26, 2019 for each of Jennifer Simpson, Barbra Keck, John Purpura, Marco Taglietti and William Rueckert, we believe that all reports were timely filed in 2019.

EQUITY COMPENSATION PLAN INFORMATION

The following table shows shares of Delcath common stock authorized for issuance under Delcath's equity compensation plan as of December 31, 2019:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	—	—	—
Equity compensation plans not approved by security holders (1)	1,640	197	502
Total	1,640	197	502

(1) Consists of grants made pursuant to the 2019 Equity Plan. The Company's 2019 Equity Incentive Plan (the "Plan") allows for grants in the form of incentive stock options, nonqualified stock options, stock units, stock awards, stock appreciation rights, and other stock-based awards. All of the Company's officers, directors, employees, consultants and advisors are eligible to receive grants under the Plan. The maximum number of shares reserved for issuance under the Plan is 2,142. Options to purchase shares of common stock are granted at exercise prices not less than 100% of fair value on the dates of grant. As of September 30, 2019, the Plan had approximately 502 shares available for grant.

Item 11. Executive Compensation.

Our Compensation Committee is responsible for formulating and establishing our overall compensation philosophy with respect to our executive officers. The Company believes that a strong executive management team comprised of talented individuals in key positions at the Company is critical to the development and growth of our business and to increasing stockholder value. Accordingly, a key objective of executive compensation is to attract and retain talented and experienced individuals, while motivating them to perform and make decisions consistent with the Company's business objectives, goals and culture. We emphasize pay-for-performance by linking executive compensation to Company performance. For each executive, the amount of pay that is actually realized is primarily driven by the Company's performance and each executive's contribution to that performance.

Our Compensation Committee considers the input it receives from our stockholders when designing and evaluating our executive compensation practices. *Compensation Components*. The three primary components of executive compensation are base salary, annual incentive cash awards and long-term equity incentive awards:

- *Base Salary.* We pay our executive officers a base salary, which our Compensation Committee reviews and determines annually. Base salaries are used to compensate our executive officers for performing the core responsibilities of their positions and to provide them with a level of security with respect to a portion of their total compensation. Base salaries are set in part based on the executive's unique skills, experience and expected contribution to the Company, as well as individual performance, including the impact of such performance on our business results, and the period of the executive's performance. Decisions regarding base salary increases take into account the executive's current base salary, third-party benchmark and survey data, and the salary compensation paid to executive officers within and outside the Company, as well as the Company's overall performance, its ability to afford such increases, its success in achieving its operational and strategic goals and objectives, and the executive officer's contribution to Company performance.
- *Annual Incentive Cash Awards.* Annual incentive compensation is intended to establish a direct correlation between annual cash awards and the performance of the Company. The Company's Annual Incentive Plan, or AIP, is an annual incentive cash bonus plan designed to align the interests of participants with the interests of the Company and its stockholders. The AIP is designed to strengthen the link between a participant's pay and his or her overall performance and the Company's performance, focus participants on critical individual and corporate objectives, offer a competitive cash incentive, and encourage and reward performance and competencies critical to the Company's success.
- *Long-Term Incentive Compensation.* In addition to using base salaries and annual incentive cash bonuses, which our Compensation Committee views as short-term compensation, a portion of our executive compensation is in the form of long-term equity compensation. Our Long-Term Incentive Plan, or LTIP, is an annual equity-based incentive plan designed to align participants' interests with those of the Company and its stockholders by rewarding participants for their contributions to the long-term success of the Company. The LTIP is designed to incentivize Company leaders to focus on the long-term performance of the Company, offer participants competitive, market-based long-term incentive award opportunities, and strengthen the link between a participant's compensation and his or her overall performance and the Company's overall long-term performance. We believe the LTIP assists us in achieving an appropriate balance between short- and long-term executive compensation.

Base Salary. The following table summarizes the amount of base salary and year-over-year increase for each of our named executive officers for 2018 and 2019:

Executive	Hire Date	2017 Base Salary	Percent Increase in 2018	2018 Base Salary	Percent Increase in 2019	2019 Base Salary
Jennifer K. Simpson, Ph.D.	3/23/2012	$ 453,004	3.0%	$ 466,594	0.0%	$ 466,594
Barbra C. Keck, M.B.A.	1/5/2009	$ 300,000	8.0%	$ 324,000	0.0%	$ 324,000
John Purpura, M.S.	11/16/2009	$ 316,210	5.9%	$ 335,000	0.0%	$ 335,000

Annual Incentive Plan. Under the AIP, annual incentive target award opportunities are expressed as a percentage of a participant's actual base salary for the performance year, beginning January 1. The following table sets forth, for each executive, the applicable target bonus percentage of base salary to which each executive is entitled.

Executive	Target Bonus Expressed as % of Base Salary	Dollars ($)	Actual Payout as % of Base Salary	Dollars ($) [1]
Jennifer K. Simpson, Ph.D.	50.0%	$ 233,297	42.5%	$ 198,302
Barbra C. Keck, M.B.A.	45.0%	$ 145,800	38.3%	$ 123,930
John Purpura, M.S.	45.0%	$ 150,750	38.3%	$ 128,138

(1) Amounts determined as of the date of this filing but have not yet been paid.

For 2019, AIP goals were based entirely on Company performance to focus all the executives on the same critical challenges facing the Company. Company performance in 2019 was measured based upon achievement of objectives in the following areas: (1) Clinical Trials and (2) Capital. The Compensation Committee has determined an overall achievement of 85.0%.

Long Term Incentive Plan. Grants under the LTIP are typically comprised of a mix of restricted stock and stock option awards granted in the first quarter of each year with the number of shares subject to the awards designed to deliver a competitive value targeted at the mid-market of the executive compensation comparison group.

These guidelines are reviewed periodically based on prevailing compensation comparison group levels, however, and the Compensation Committee then uses these guidelines to determine long-term equity incentive awards for our named executive officers based upon a holistic assessment of Company and individual performance for the prior year and its view of the appropriate incentives to best help achieve the Company's business objectives. Our ability to provide awards at the mid-market level has been difficult to do in the past few years due to share availability. Such awards in the past few years have typically been at or below the market 25th percentile.

Summary Compensation Table.

The following table sets forth the total compensation awarded to, earned by or paid to: (i) each person who served as a principal executive officer during 2019, and (ii) our two other most highly-compensated executive officers who were serving as executive officers on December 31, 2019. We refer to these individuals as our "named executive officers."

Name and Position	Year	Salary ($)(1)	Bonus ($)(2)	Stock Awards ($)(3)	Options Awards ($)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Jennifer K. Simpson, Ph.D.	2019	$ 466,594	$ 508,495	$ —	$ 90,706	$ —	$ —	$ 1,065,795
President and Chief Executive Officer	2018	466,594	75,000	—	—	—	—	541,594
Barbra C. Keck, M.B.A.	2019	324,000	311,449	—	64,790	—	—	700,239
Chief Financial Officer and Secretary	2018	324,000	50,000	—	—	—	—	374,000
John Purpura, M.S.	2019	335,000	288,151	—	59,390	—	—	682,541
Executive Vice President, Global Head of Operations	2018	335,000	50,000	—	—	—	—	385,000

(1) For 2019, Dr. Simpson was paid $393,703, Ms. Keck was paid $274,875 and Mr. Purpura was paid $284,042. For 2018, Dr. Simpson was paid $172,142, Ms. Keck was paid $116,500 and Mr. Purpura was paid $135,669. The balance of their salaries has been accrued.

(2) For 2018 and 2019, all bonus amounts have been accrued and not yet paid. For 2019, each NEO was awarded an annual incentive award, a bonus related to the Private Placements and a Retention Bonus.

(3) Due to the lack of available shares for issuance under the Company's 2009 Stock Incentive Plan, the Board of Directors did not grant any long-term equity awards to our named executive officers in 2018 which in no way should create any negative inference concerning the Compensation Committee's evaluation of their performance.

Grants of Plan-Based Awards—2019

The following table sets forth grants of plan-based awards made during the fiscal year ended December 31, 2019 to the named executive officers. All equity grants were made pursuant to the Company's 2019 Equity Incentive Plan, or the 2019 Plan. Under the 2019 Plan, 2,142 shares of common stock of the Company are available for grants through February 1, 2029 to the Company's employees, directors and consultants. The stock options are vesting over a period of one year commencing from the date of grant in twelve equal monthly increments commencing on the one month anniversary of the grant date. The stock options carry a ten year term and expire on February 1, 2029.

Name	Grant Date	All Other Option Awards; Number of Securities Underlying Options	Option Exercise Price	Grant Date Fair Value of Option Award
Jennifer K. Simpson, Ph.D.	2/1/2019	500	$ 196.70	$ 90,706
Barbra C. Keck, M.B.A.	2/1/2019	357	$ 196.70	$ 64,790
John Purpura, M.S.	2/1/2019	357	$ 196.70	$ 64,790

Outstanding Equity Awards at Fiscal Year-End Table—2019.

The following table sets forth information relating to unexercised options and unvested restricted shares held by the named executive officers as of December 31, 2019.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested ($)
Jennifer K. Simpson, Ph.D.	458	42	$ 196.70	2/1/2029	42	—
Barbra C. Keck, M.B.A.	327	30	$ 196.70	2/1/2029	30	—
John Purpura, M.S.	327	30	$ 196.70	2/1/2029	30	—

Potential Payments upon Termination or Change of Control.

The following table shows the potential incremental value transfer to each named executive officer under various termination or change-in-control scenarios as of December 31, 2019, the last business day of 2019. Unvested, unexercised stock options and unvested restricted stock awards are valued at the closing market price of our common stock on that date. The actual amounts to be paid out in respect of the named executive officers can only be determined at the time of such named executive officer's actual separation from our company.

Name	Retirement or Voluntary Termination Without "Good Reason"	Termination for "Cause"	Involuntary Termination (Termination Without Cause, or Termination for Good Reason)	Upon a Change in Control	Death or Disability Termination
Jennifer K. Simpson, Ph.D.	—	—	$ 730,661	$ 730,661	—
Barbra C. Keck, M.B.A.	—	—	$ 536,029	$ 536,029	—
John Purpura, M.S.	—	—	$ 520,733	$ 520,733	—

Severance Arrangements

The Company has entered into an Executive Security Agreement with each of the named executive officers. The Executive Security Agreements provide for the payment of severance to each of our named executive officers upon a qualifying termination (a termination which is involuntary but not "for cause" or a termination for "good reason" as defined therein) to be paid within 10 days of such event as follows: (i) all base salary owed to the date of the qualifying event, (ii) a one-time lump sum fee equal to the named executive officer's monthly base salary for a term of two years for Jennifer Simpson and 18 months for Barbra Keck and John Purpura, and (iii) COBRA payments should the named executive officer remain on the Company's health benefit plans. The named executive officer would also be entitled to a pro-rata portion of any AIP payment for the fiscal year in which termination of

employment occurs due by March 15th of the following year. The term of the Executive Security Agreements continues until terminated by mutual agreement of each named executive officer and the Company.

Director Compensation—2019

The Compensation Committee reviews and recommends to the Board of Directors appropriate director compensation programs for service as directors, committee chairs, and committee members.

In lieu of per-meeting fees, non-employee directors of the Company are paid an annual retainer of $43,000 and certain additional annual retainers for chairing or serving as a member of the committees of the Board as follows:

Name	Annual Retainer
Board Service	$ 43,000
Chair of Audit Committee	$ 20,000
Member of Audit Committee	$ 8,000
Chair of Compensation and Stock Option Committee	$ 12,000
Member of Compensation and Stock Option Committee	$ 5,000
Chair of Nominating and Corporate Governance Committee	$ 8,000
Member of Nominating and Corporate Governance Committee	$ 4,000

Dr. Stoll receives an annual retainer fee as Director and Chairman of the Board of $68,000. Additionally, we reimburse all non-employee directors for their reasonable out-of-pocket travel expenses incurred in attending meetings of our Board of Directors or any committees of the Board.

The following table sets forth the compensation awarded to, earned by or paid to each non-employee director who served on our Board of Directors in 2019.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards	All Other Compensation	Total
Simon Pedder, Ph.D. (1)	$ 14,000	$ —	$ —	$ —	$ 14,000
William D. Rueckert	72,000	—	25,916	—	97,916
Roger G. Stoll, Ph.D.	87,750	—	25,916	—	113,666
John Sylvester	21,161	—	—	—	21,161
Marco Taglietti, M.D.	65,000	—	25,916	—	90,916

(1) Dr. Pedder resigned as a director effective April 10, 2019. John R. Sylvester was appointed director effective July 24, 2019 to fill the vacancy created.
(2) No non-employee director was paid his 2018 fees. Certain amounts were invested by directors in the July 2019 Private Placement. Mr. Rueckert and Dr. Taglietti have not been paid their 2019 fees. Their fees have been accrued.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Based solely upon information made available to us, the following table sets forth information regarding the beneficial ownership of our common stock, Series E Preferred Stock and Series E-1 Preferred Stock as of March 25, 2020, held by: (i) each director and director nominees; (ii) each of the named executive officers; (iii) all of our directors and executive officers as a group; and (iv) each additional person or group who is known by us to own beneficially more than 5% of our common stock or Series E and Series E-1 Preferred Stock. Except as indicated in the footnotes below, the address of the persons or groups named below is c/o Delcath Systems, Inc., 1633 Broadway, Suite 22C, New York, New York 10019.

	Shares Beneficially Owned (1)							
Name of Beneficial Owner	Common Stock		Percent	Series E Preferred Stock		Percent	Series E-1 Preferred Stock	Percent
Named Executive Officers and Directors:								
Jennifer K. Simpson, Ph.D.	6,892	(2)	9.5%	147	(3)	*	—	—
Barbra C. Keck, M.B.A.	3,322	(4)	4.4%	68	(5)	*	—	—
John Purpura, M.S.	3,187	(6)	4.2%	65	(7)	*	—	—
William D. Rueckert	2,761	(8)	3.7%	60	(9)	*	—	—
Roger G. Stoll, Ph.D.	4,189	(10)	5.4%	93	(11)	*	—	—
Marco Taglietti, M.D.	2,748	(12)	3.6%	60	(13)	*	—	—
Elizabeth Czerepak	—		*	—		*	—	—
John Sylvester	—		*	—		*	—	—
All directors and executive officers as a group (8 people):	23,099	(14)	30.8%	493	(15)	1.5%	—	—
5% Stockholders								
Altium Capital Management, LP (16) Altium Growth Fund, LP Altium Growth GP, LLC 551 Fifth Ave, FL 19 New York, NY 10176	7,204		9.9%	2,300		7.2%	1,100	11.7%
Rosalind Master Fund L.P. (17) Rosalind Opportunities Fund I L.P. 77 Bloor St W, 3rd FL Toronto, Ontario M5S 1M2	7,204		9.9%	16,800		52.4%	2,875	30.6%
Hudson Bay Master Fund Ltd (18) 777 Third Avenue, 30th Floor New York, NY 10017	7,204		9.9%	2,187		6.8%	—	0.0%

* Less than 1%

(1) (i) except as otherwise indicated in these footnotes, each stockholder named in the table above possesses sole voting and investment power with respect to all shares of common stock, Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock beneficially owned by him, her or it, (ii) the number of shares of common stock beneficially owned by each stockholder shown above has been determined in accordance with Rule 13d-3 under the Exchange Act and includes, for such purpose, shares of common stock that such stockholder has the right to acquire within 60 days of March 25, 2020 after giving effect to any applicable limitations on beneficial ownership described in the footnotes below, or Beneficial Ownership Limitation, and (iii) the beneficial ownership percentages shown above are based on 72,773 shares of common stock, 32,061 shares of Series E Preferred Stock, and 9,385 shares of Series E-1 Preferred Stock outstanding as of March 25, 2020, respectively. Shares of Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock vote together with the common stock on an as-converted basis, subject to any applicable Beneficial Ownership Limitation, on all matters submitted to holders of common stock for approval.

(2) Includes 500 shares of common stock, which Dr. Simpson has the right to acquire upon exercise of outstanding options exercisable within 60 days of March 25, 2020.

(3) The 147 shares of Series E Convertible Preferred Stock are convertible into 6,381 shares of common stock subject to the Beneficial Ownership Limitation and does not include the 6,381 shares of common stock that may be obtained by Dr. Simpson upon the exercise of a warrant held by her, which is subject to the Beneficial Ownership Limitation.

(4) Includes 357 shares of common stock, which Ms. Keck has the right to acquire upon exercise of outstanding options exercisable within 60 days of March 25, 2020.

(5) The 68 shares of Series E Convertible Preferred Stock are convertible into 2,952 shares of common stock subject to the Beneficial Ownership Limitation and does not include the 2,952 shares of common stock that may be obtained by Ms. Keck upon the exercise of a warrant held by her, which is subject to the Beneficial Ownership Limitation.

(6) Includes 357 shares of common stock, which Mr. Purpura has the right to acquire upon exercise of outstanding options exercisable within 60 days of March 25, 2020.

(7) The 65 shares of Series E Convertible Preferred Stock are convertible into 2,822 shares of common stock subject to the Beneficial Ownership Limitation and does not include the 2,822 shares of common stock that may be obtained by Mr. Purpura upon the exercise of a warrant held by him, which is subject to the Beneficial Ownership Limitation.

(8) Includes 142 shares of common stock, which Dr. Stoll has the right to acquire upon exercise of outstanding options exercisable within 60 days of March 25, 2020.

(9) The 93 shares of Series E Convertible Preferred Stock are convertible into 4,037 shares of common stock subject to the Beneficial Ownership Limitation and does not include the 4,037 shares of common stock that may be obtained by Mr. Stoll upon the exercise of a warrant held by him, which is subject to the Beneficial Ownership Limitation.

(10) Includes 142 shares of common stock, which Mr. Rueckert has the right to acquire upon exercise of outstanding options exercisable within 60 days of March 25, 2020.

(11) The 60 shares of Series E Convertible Preferred Stock are convertible into 2,605 shares of common stock subject to the Beneficial Ownership Limitation and does not include the 2,605 shares of common stock that may be obtained by Mr. Rueckert upon the exercise of a warrant held by him, which is subject to the Beneficial Ownership Limitation.

(12) Includes 142 shares of common stock, which Dr. Taglietti has the right to acquire upon exercise of outstanding options exercisable within 60 days of March 25, 2020.

(13) The 60 shares of Series E Convertible Preferred Stock are convertible into 2,605 shares of common stock subject to the Beneficial Ownership Limitation and does not include the 2,605 shares of common stock that may be obtained by Mr. Taglietti upon the exercise of a warrant held by him, which is subject to the Beneficial Ownership Limitation.

(14) Includes 1,640 shares of common stock, which certain directors and executive officers have the right to acquire upon exercise of outstanding options exercisable within 60 days of March 25, 2020.

(15) The aggregate 493 shares of Series E Convertible Preferred Stock are convertible into an aggregate of 21,402 shares of common stock subject to the Beneficial Ownership Limitation and does not include the aggregate 21,402 shares of common stock that may be obtained by such persons upon the exercise of warrants held by them, subject to the Beneficial Ownership Limitation.

(16) The information provided is based on a Statement on Schedule 13G/A jointly filed on February 14, 2020 by and on behalf of each of Altium Growth Fund, LP, Altium Capital Management, LP, and Altium Growth GP, LLC which acquired shares of Series E Preferred Stock and warrants in our July 2019 PIPE Financing. Altium Growth Fund, LP is the record and direct beneficial owner of the securities referenced. Altium Capital Management, LP is the investment adviser of, and may be deemed to beneficially own securities, owned by, Altium Growth Fund, LP. Altium Growth GP, LLC is the general partner of, and may be deemed to beneficially own securities owned by, Altium Growth Fund, LP. The reporting persons hold shared voting and dispositive power with respect to 2,300 shares of Series E Convertible Preferred Stock and 1,100 shares of Series E-1 Convertible Preferred Stock which could be converted into 134,069 shares of common stock or that may be voted pursuant to the as-converted voting provisions of the Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock subject to the Blockers described below. The referenced securities do not include 134,069 shares of common stock that may be obtained upon the exercise of warrants held by the reporting persons subject to the Blockers described below. Each reporting person disclaims beneficial ownership of the securities referenced. Each of the reporting persons may be deemed to be a member of a group with respect to Delcath or securities of Delcath for the purposes of Section 13(d) or 13(g) of the Securities Act of 1933, as amended. Pursuant to the terms of (i) the certificate of designations of Delcath containing the terms of the Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock, the reporting persons cannot convert their shares of Series E Convertible Preferred Stock or Series E-1 Convertible Preferred Stock to the extent the reporting persons would beneficially own, after any such conversion, more than 9.99% of the outstanding shares of common stock, or the Preferred Stock Blockers, and (ii) the as to the warrants referenced, the reporting persons cannot exercise such warrants to the extent the reporting persons would beneficially own, after any such exercise, more than 4.99% of the outstanding shares of common stock, or the Warrant Blockers, and collectively with the Preferred Stock Blockers, the Blockers, and the percentage set forth above gives effect to the Blockers. Consequently, as of March 25, 2020, the reporting persons were not able to exercise all of the reported Series E Convertible Preferred Stock, the Series E-1 Convertible Preferred Stock or any of the reported warrants due to the Blockers.

(17) The information provided is based on a Statement on Schedule 13G/A jointly filed on March 6, 2020 by and on behalf of Rosalind Advisors, Inc., Rosalind Opportunities Fund I L.P., Rosalind Master Fund L.P. and Steven Salamon with respect to beneficial ownership of shares of Series E Convertible Preferred Stock and warrants acquired in our July 2019 PIPE Financing. Rosalind Advisors, Inc., or the Advisor, is the investment advisor to Rosalind Opportunities Fund I L.P. and Rosalind Master Fund L.P. and may be deemed to be the beneficial owner of shares held by Rosalind Opportunities Fund I L.P. and Rosalind Master Fund L.P. Steven Salamon is the portfolio manager of the Advisor and may be deemed to be

the beneficial owner of shares of Series E Convertible Preferred Stock and underlying warrants for common stock held by Rosalind Master Fund L.P. The Rosalind Opportunities Fund I L.P. holds shared voting and dispositive power with respect to 10,400 shares of Series E Convertible Preferred Stock and 2,260 shares of Series E-1 Convertible Preferred Stock that can be converted into 549,479 shares of common stock or that may be voted pursuant to the as-converted voting provisions of the Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock subject to the Blockers described below. The Rosalind Master Fund L.P. holds shared dispositive and voting power with respect to 6,400 shares of Series E Convertible Preferred Stock and 615 shares of Series E-1 Convertible Preferred Stock that could be converted into 304,471 shares of common stock or that may be voted pursuant to the as-converted voting provisions of the Series E Convertible Preferred Stock subject to the Blockers described below. The Advisor and Steven Salamon hold shared voting and dispositive power with respect to 19,675 shares of Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock that could be converted into 853,950 shares of common stock or that may be voted pursuant to the as-converted voting provisions of the Series E Convertible Preferred Stock or Series E-1 Convertible Preferred Stock subject to the Blockers described below. Notwithstanding the foregoing, the Advisor and Mr. Salamon disclaim beneficial ownership of any such shares. The referenced securities do not include 853,950 shares of common stock that may be obtained upon the exercise of warrants held by the reporting persons subject to the Blockers described below. Each reporting person disclaims beneficial ownership of the securities referenced. Each of the reporting persons may be deemed to be a member of a group with respect to Delcath or securities of Delcath for the purposes of Section 13(d) or 13(g) of the Securities Act of 1933, as amended. Pursuant to the terms of (i) the certificate of designations of Delcath containing the terms of the Series E Convertible Preferred Stock or the Series E-1 Convertible Preferred Stock, the reporting persons cannot convert their shares of Series E Convertible Preferred Stock or Series E-1 Convertible Preferred Stock to the extent the reporting persons would beneficially own, after any such conversion, more than 9.99% of the outstanding shares of common stock, or the Preferred Stock Blockers, and (ii) as to the warrants referenced, the reporting persons cannot exercise such warrants to the extent the reporting persons would beneficially own, after any such exercise, more than 4.99% of the outstanding shares of common stock, or the Warrant Blockers, and collectively with the Preferred Stock Blockers, the Blockers, and the percentage set forth above gives effect to the Blockers. Consequently, as of March 25, 2020, the reporting persons were not able to exercise all of the reported Series E Convertible Preferred Stock or Series E-1 Convertible Preferred Stock or any of the reported warrants due to the Blockers.

(18) Based on the information available to the Company, Hudson Bay Master Fund Ltd, which acquired shares of Series E Convertible Preferred Stock, Series E-1 Convertible Preferred Stock, Series E Warrants and Series E-1 Warrants in our July and August 2019 PIPE financings. Hudson Bay Master Fund Ltd is the record and direct beneficial owner of the securities referenced. Hudson Bay Capital Management LP, the investment manager of Hudson Bay Master Fund Ltd., has voting and investment power over these securities. Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management LP. Hudson Bay Capital Management LP may be deemed to be the beneficial owner of all shares of common stock underlying the securities held by Hudson Bay Master Fund Ltd. Mr. Gerber disclaims beneficial ownership of these securities. Hudson Bay Capital Management LP holds sole voting and dispositive power with respect to 2,187 shares of Series E Convertible Preferred Stock could be converted into 94,927 shares of common stock or that may be voted pursuant to the as-converted voting provisions of the Series E Convertible Preferred Stock or Series E-1 Convertible Preferred Stock subject to the Blockers described below. The referenced securities do not include 106,866 shares of common stock that may be obtained upon the exercise of warrants held by the reporting persons subject to the Blockers described below. Each reporting person disclaims beneficial ownership of the securities referenced. Pursuant to the terms of (i) the certificate of designations of Delcath containing the terms of the Series E Convertible Preferred Stock or Series E-1 Convertible Preferred Stock, the reporting persons cannot convert their shares of Series E Convertible Preferred Stock to the extent the reporting persons would beneficially own, after any such conversion, more than 9.99% of the outstanding shares of common stock, or the Preferred Stock Blockers, and (ii) as to the warrants referenced, the reporting persons cannot exercise such warrants to the extent the reporting persons would beneficially own, after any such exercise, more than 9.99% of the outstanding shares of common stock, or the Warrant Blockers, and collectively with the Preferred Stock Blockers, the Blockers, and the percentage set forth above gives effect to the Blockers. Consequently, as of March 25, 2020, the reporting persons were not able to exercise all of the reported Series E Convertible Preferred Stock, Series E-1 Convertible Preferred Stock or any of the reported warrants due to the Blockers.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Transactions with Related Persons. We have adopted a written policy for the review and approval or ratification of transactions between our company and Related Parties (as defined below). Under the policy, our Nominating Committee will review the material facts of proposed transactions involving Delcath in which a Related Party will have a direct or indirect material interest. The Nominating Committee will either approve or disapprove our entry into the transaction or, if advance approval is not feasible, will consider whether to ratify the transaction. The Nominating Committee may establish guidelines for ongoing transactions with a Related Party, and will review such transactions at least annually. If the aggregate amount of the transaction is expected to be less than $200,000, such approval or ratification may be made by the Chair of the Committee. In determining whether to approve or ratify a transaction with a Related Party, the Nominating Committee (or Chair) will consider, among other factors, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third-party and the extent of the Related Party's interest in the transaction.

Certain transactions are deemed pre-approved under the policy, including compensation of executive officers and directors (except that employment of an immediate family member of an executive officer requires specific approval), and transactions with a company at which the Related Party's only relationship is as a non-officer employee, director, or less than 10% owner if the aggregate amount involved does not exceed 2% of such company's total annual revenues (or, in the case of charitable contributions by us, 1% of the charity's total annual receipts). Pre-approval is not required if the amount involved in the transaction is not expected to exceed $120,000 in any calendar year.

For purposes of the policy, a Related Party is generally anyone who since the beginning of the last full fiscal year is or was an executive officer, director or director nominee, owner of more than 5% of our common stock, or immediate family member of any of such persons.

Except for the participation of certain Related Parties in the Private Placements and the Debt Exchange, no Related Party transactions occurred during 2019 and 2018.

The Board has affirmatively determined that five of our six directors are independent directors. For further information regarding the independence of our directors, please see the discussion under "Item 10 – Directors, Executive Officers and Corporate Governance-Corporate Governance."

Certain Anti-Takeover Provisions of Delaware Law and our Certificate of Incorporation and Bylaws

We are not subject to Section 203 of the Delaware General Corporation Law, which prohibits Delaware corporations from engaging in a wide range of specified transactions with any interested stockholder, defined to include, among others, any person other than such corporation and any of its majority owned subsidiaries who own 15% or more of any class or series of stock entitled to vote generally in the election of directors, unless, among other exceptions, the transaction is approved by (i) our board of directors prior to the date the interested stockholder obtained such status or (ii) the holders of two-thirds of the outstanding shares of each class or series of stock entitled to vote generally in the election of directors, not including those shares owned by the interested stockholder.

Staggered Board of Directors

Our certificate of incorporation and by-laws provide that our board of directors be classified into three classes of directors of approximately equal size. As a result, in most circumstances, a person can gain control of our board only by successfully engaging in a proxy contest at two or more annual meetings.

Authorized But Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, corporate acquisitions, employee benefit plans and stockholder rights plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Item 14. Accounting Fees and Services.

The aggregate fees billed by Marcum LLP for services rendered as our independent registered public accounting firm during the fiscal years ended December 31, 2019 and 2018, respectively:

	Fiscal Year	
	2019	2018
Audit Fees	$ 286,907	$ 104,063
Audit-Related Fees	—	—
Tax Fees	—	—
Total	$ 286,907	$ 104,063

Audit Fees. These are fees for services rendered in connection with the audit of the annual financial statements included in our annual reports on Forms 10-K; the review of the financial statements included in our Quarterly Reports on Forms 10-Q; the audit of our internal control over financial reporting; and for services that are normally provided by an independent auditor in connection with statutory and regulatory filings or engagements.

Audit-Related Fees. Marcum did not perform any assurance and related services that were reasonably related to the performance of the audit or review of our financial statements for the years ended December 31, 2019 and 2018.

Tax Fees. Marcum did not perform any tax compliance services for us during the years ended December 31, 2019 and 2018.

All Other Fees. Marcum did not receive any other fees from us for the years ended December 31, 2019 and 2018.

Pre-approval Policies: Audit and Non-Audit Services. The Audit Committee pre-approves all audit services and the terms of such services and permissible non-audit services provided by Delcath's independent registered public accounting firm, prior to its engagement for the provision of such services. The Chair of the Audit Committee has been delegated the authority by the committee to pre-approve interim services by Delcath's independent registered public accounting firm; provided the Chair reports all such pre-approvals to the entire Audit Committee at the next Committee meeting. There were no non-audit services provided to Delcath by our independent registered public accounting firm for 2019 and 2018 that required review by the Audit Committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Annual Report on Form 10-K:

1. ***Consolidated Financial Statements***: The following Consolidated Financial Statements and Supplementary Data of Delcath and the Report of Independent Registered Public Accounting Firm included in Part II, Item 8:
    - Consolidated Balance Sheets at December 31, 2019 and 2018
    - Consolidated Statements of Comprehensive Loss for the years ended December 31, 2019 and 2018
    - Consolidated Statements of Stockholders' Equity for the years ended December 31, 2019 and 2018
    - Consolidated Statements of Cash Flows for the years ended December 31, 2019 and 2018
    - Notes to Consolidated Financial Statements
2. ***Exhibits***: The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this Annual Report on Form 10-K.

Item 16. Form 10-K Summary.

None.

Exhibit Index

Exhibit No.		Description
3.1		Amended and Restated Certificate of Incorporation of Company (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1/A filed September 25, 2019).
3.2		Amendment to the Amended and Restated Certificate of Incorporation of the Company dated October 17, 2019 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 23, 2019).
3.3		Certificate of Correction to Amendment to the Amended and Restated Certificate of Incorporation of the Company dated October 22, 2019 (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on October 23, 2019).
3.4		Amendment to the Amended and Restated Certificate of Incorporation of the Company, effective December 24, 2019 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 30, 2019).
3.5		Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to Company's Registration Statement on Form SB-2).
4.1		Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock of Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed July 11, 2019).
4.2		Certificate of Designation of Preferences, Rights and Limitations of Series E-1 Convertible Preferred Stock of Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed August 16, 2019).
4.3		Form of Series E Warrant to Purchase Shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed July 11, 2019).
4.4		Form of Series E-1 Warrant to Purchase Shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed August 16, 2019).
4.5		Form of Registration Rights Agreement between the Company and each other party a signatory thereto (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed July 11, 2019).
4.6		Form of Registration Rights Agreement between the Company and each other party a signatory thereto (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed August 16, 2019).
4.7		Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.7 to the Company's Amendment No. 1 to Form S-1 filed February 7, 2020).
4.8	**	Description of Securities.
10.1		2009 Stock Incentive Plan (incorporated by reference to Appendix B to the Company's definitive Proxy Statement dated April 30, 2009).
10.2		Form of Indemnification Agreement dated April 8, 2009 between the Company and members of the Company's Board of Directors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 10, 2009).
10.3		Lease between SLG 810 Seventh Lessee LLC and the Company dated as of February 5, 2010 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010).
10.4		Amended and Restated Supply Agreement between B. Braun Medical Inc and the Company dated as of May 4, 2010 (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010).
10.5		Lease Modification, Extension and Additional Space Agreement between SLG 810 Seventh Lessee LLC and the Company dated as of September 27, 2010 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 30, 2010).

Exhibit No.	Description
10.6	License, Supply and Contract Manufacturing Agreement between Synerx Pharma, LLC and Bioniche Teoranta and the Company dated as of October 13, 2010 (incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010).
10.7	Form of Employee Confidentiality and Restrictive Covenant Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed September 26, 2011).
10.8	Lease Agreement dated August 2, 2011 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011).
10.9	Sublease between Delcath Systems, Inc. and SLG 810 Seventh Lessee LLC, dated May 22, 2014. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 28, 2014).
10.10	Sublease Agreement between Delcath Systems, Inc. and ICV Partners, LLC dated August 18, 2014 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 30, 2014).
10.11	Form of Warrant Repurchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 3, 2017).
10.12	Exchange Agreement dated July 2, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 2, 2017).
10.13	Securities Purchase Agreement dated July 5, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 6, 2017).
10.14	Form of Leak-Out Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 2, 2017).
10.15	Amended and Restated Securities Purchase Agreement dated July 5, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed on July 12, 2017).
10.16	Form of Restructuring Agreement and Warrant (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 28, 2017).
10.17	Securities Purchase Agreement dated September 19, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 21, 2017).
10.18	Exchange Agreement,dated November 15, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 16, 2017).
10.19	Form of Exchange Note (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 16, 2017).
10.20	Form of Exchange Warrant (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on November 16, 2017).
10.21	Exchange Agreement,dated December 28, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 29, 2017).
10.22	Form of Leak-Out Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 29, 2017).
10.23	Executive Agreement between the Company and Jennifer Simpson (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 26, 2018).
10.24	Executive Agreement between the Company and Barbra Keck (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on March 26, 2018).

Exhibit No.	Description
10.25	Executive Agreement between the Company and John Purpura (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on March 26, 2018).
10.26	Securities Purchase Agreement dated as of June 4, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 8, 2018).
10.27	First Amendment to Securities Purchase Agreement dated as of July 20, 2018 to Securities Purchase Agreement dated as of June 4, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 26, 2018).
10.28	First Amendment to Warrants to Purchase Common Stock dated July 20, 2018 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 26, 2018).
10.29	Form of Securities Purchase Agreement dated August 31, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 7, 2018).
10.30	Form of Backstop Commitment Purchase Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 7, 2018).
10.31	Form of 8% Senior Secured Convertible Promissory Note (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on September 7, 2018).
10.32	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on September 7, 2018).
10.33	Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on September 7, 2018)
10.34	Form of First Amendment to 8% Senior Secured Convertible Promissory Notes issued June 4, 2018 (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed on September 7, 2018).
10.35	Form of Second Amendment to Warrants to Purchase Common Stock issued June 4, 2018 and July 20, 2018 (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed on September 7, 2018).
10.36	Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on September 7, 2018).
10.37	Form of Second Amendment to Warrants to Purchase Common Stock issued June 4, 2018 and July 20, 2018 (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed on September 7, 2018).
10.38	Form of Stock Purchase Agreement dated as of November 16, 2018 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed November 7, 2018).
10.39	License, Supply and Marketing Agreement for CHEMOSAT® dated as of December 10, 2018 between the Company and medac Gesellschaft für klinische Spezialpräparate mbH (incorporated by reference to Exhibit 10.38 to the Company's Form 10-K filed on June 14, 2019).†
10.40	Form of Exchange Agreement dated December 2018 (incorporated by reference to Exhibit 10.39 to the Company's Form 10-K filed on June 14, 2019).
10.41	Form of Leak-Out Agreement dated December 2018 (incorporated by reference to Exhibit 10.40 to the Company's Form 10-K filed on June 14, 2019).
10.42	2019 Equity Incentive Plan (incorporated by reference to Exhibit 4.01 to the Company's Current Report on Form 8-K filed on February 7, 2019).
10.43	Global Settlement Agreement dated as of April 18, 2019 by and among the Company, Iroquois Capital Investment Group, LLC, Iroquois Master Fund Ltd. and FirstFire Global Opportunities Fund LLC (incorporated by reference to Exhibit 10.42 to the Company's Form 10-K filed on June 14, 2019).

Exhibit No.		Description
10.44		Securities Purchase Agreement dated as of April 19, 2019 (incorporated by reference to Exhibit 10.43 to the Company's Form 10-K filed on June 14, 2019).
10.45		Securities Purchase Agreement dated as of April 26, 2019 (incorporated by reference to Exhibit 10.44 to the Company's Form 10-K filed on June 14, 2019).
10.46		Securities Purchase Agreement dated as of May 9, 2019 (incorporated by reference to Exhibit 10.45 to the Company's Form 10-K filed on June 14, 2019).
10.47		Securities Purchase Agreement dated as of May 23, 2019 (incorporated by reference to Exhibit 10.46 to the Company's Form 10-K filed on June 14, 2019).
10.48		Note Purchase Agreement dated as of June 6, 2019 by and among Delcath Systems, Inc., Rosalind Master Fund LP and Rosalind Opportunities Fund I (incorporated by reference to Exhibit 10.47 to the Company's Form 10-K filed on June 14, 2019).
10.49		Form of 8% Secured Promissory Note Due June 6, 2021 (incorporated by reference to Exhibit 10.48 to the Company's Form 10-K filed on June 14, 2019).
10.50		Securities Purchase Agreement dated as of July 11, 2019 between the Company and Roth Capital Partners, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 11, 2019).
10.51		Engagement Letter dated as of May 20, 2019 between the Company and Roth Capital Partners, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 11, 2019).
10.52		Securities Purchase Agreement dated as of August 15, 2019 between the Company and Roth Capital Partners, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 16, 2019).
10.53		Engagement Letter dated as of August 14, 2019 between the Company and Roth Capital Partners, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed August 16, 2019).
10.54		Amendment dated as of August 15, 2019 between the Company and each purchaser a signatory thereto to Securities Purchase Agreement dated as of July 11, 2019 between the Company and the purchasers signatories thereto (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed August 16, 2019).
31.1	**	Certification by Principal executive officer Pursuant to Rule 13a 14.
31.2	**	Certification by Principal financial officer Pursuant to Rule 13a 14.
32.1	**	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	**	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.CAL	**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	**	XBRL Taxonomy Extension Definition Linkbase Document
101.INS	**	XBRL Instance Document
101.LAB	**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	**	XBRL Taxonomy Extension Presentation Linkbase Document
101.SCH	**	XBRL Taxonomy Extension Schema

† Portions of this exhibit have been omitted.
* Indicates management contract or compensatory plan or arrangement.

** Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DELCATH SYSTEMS, INC.

/s/ Jennifer K. Simpson
Jennifer K. Simpson
President and Chief Executive Officer
(Principal Executive Officer)
Dated: March 25, 2020

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jennifer K. Simpson Jennifer K. Simpson	President and Chief Executive Officer and Director (Principal Executive Officer)	March 25, 2020
/s/ Barbra C. Keck Barbra C. Keck	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 25, 2020
/s/ Roger G. Stoll, Ph.D. Roger G. Stoll, Ph.D.	Chairman of the Board	March 25, 2020
/s/ Elizabeth Czerepak Elizabeth Czerepak	Director	March 25, 2020
/s/ William Rueckert William Rueckert	Director	March 25, 2020
/s/ John R. Sylvester John R. Sylvester	Director	March 25, 2020
/s/ Marco Taglietti Marco Taglietti	Director	March 25, 2020

EXHIBIT 4.8

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of our common stock and preferred stock summarizes the material terms and provisions of our common stock and preferred stock. The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our Amended and Restated Certificate of Incorporation, as amended, (the "Certificate of Incorporation") and our Amended and Restated By-Laws, as amended, (the "Bylaws") which are exhibits to the Annual Report on Form 10-K filed with the Securities and Exchange Commission, of which this Exhibit [4.8] forms a part, and by applicable law. The terms of our common stock and preferred stock may also be affected by Delaware law.

Our authorized capital stock consists of:

- 1,000,000,000 shares of common stock, par value $0.01 per share;
- 10,000,000 shares of undesignated preferred stock, par value $0.01 per share.

As of March 9, 2020, we had (a) 72,773 shares of common stock issuable upon the exercise of outstanding warrants, including (i) 29 common stock warrants and (ii) 1,826,579 Series E and Series E-1 Warrants at a weighted average exercise price of $23.04 per share and (b) 1,502 shares of common stock issuable upon the exercise of outstanding options with a weighted average exercise price of $196.70 per share.

Description of Common Stock

Voting

Holders of our common stock are entitled to one vote per share on matters to be voted on by stockholders and also are entitled to receive such dividends, if any, as may be declared from time to time by our board of directors in its discretion out of funds legally available therefor. Holders of our common stock have exclusive voting rights for the election of our directors and all other matters requiring stockholder action, except with respect to amendments to our Certificate of Incorporation that alter or change the powers, preferences, rights or other terms of any outstanding preferred stock if the holders of such affected series of preferred stock are entitled to vote on such an amendment or filling vacancies on the board of directors.

Dividends

Holders of common stock are entitled to share ratably in any dividends declared by our board of directors, subject to any preferential dividend rights of any outstanding preferred stock. Dividends consisting of shares of common stock may be paid to holders of shares of common stock. We do not intend to pay cash dividends in the foreseeable future.

Liquidation and Dissolution

Upon our liquidation or dissolution, the holders of our common stock will be entitled to receive pro rata all assets remaining available for distribution to stockholders after payment of all liabilities and provision for the liquidation of any shares of preferred stock at the time outstanding.

Other Rights and Restrictions

Our common stock has no preemptive or other subscription rights, and there are no conversion rights or redemption or sinking fund provisions with respect to such stock. Our common stock is not subject to redemption by us. Our Certificate of Incorporation and Bylaws do not restrict the ability of a holder of common stock to transfer the stockholder's shares of common stock. If we issue shares of common stock under this prospectus, the shares will be fully paid and non-assessable and will not have, or be subject to, any preemptive or similar rights.

Market Information

Our common stock is quoted the OTCQB under the symbol “DCTH”.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Certain provisions of our Certificate of Incorporation and Bylaws could have the effect of making it more difficult for our stockholders to replace management at a time when a substantial number of stockholders might favor a change in management. These provisions include:

- providing for a staggered board; and
- authorizing the board of directors to fill vacant directorships or increase the size of its board of directors.

Furthermore, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval. Any series of preferred stock is likely to be senior to the common stock with respect to dividends, liquidation rights and, possibly, voting rights. The board’s ability to issue preferred stock may have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock.

We are not subject to Section 203 of the Delaware General Corporation Law, which prohibits Delaware corporations from engaging in a wide range of specified transactions with any interested stockholder, defined to include, among others, any person other than such corporation and any of its majority owned subsidiaries who own 15% or more of any class or series of stock entitled to vote generally in the election of directors, unless, among other exceptions, the transaction is approved by (i) our board of directors prior to the date the interested stockholder obtained such status or (ii) the holders of two-thirds of the outstanding shares of each class or series of stock entitled to vote generally in the election of directors, not including those shares owned by the interested stockholder.

Staggered Board of Directors

Our Certificate of Incorporation and Bylaws provide that our board of directors be classified into three classes of directors of approximately equal size. As a result, in most circumstances, a person can gain control of our board only by successfully engaging in a proxy contest at two or more annual meetings.

Authorized But Unissued Shares

Our authorized but unissued shares of preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, corporate acquisitions, employee benefit plans and stockholder rights plans. The existence of authorized but unissued and unreserved preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Description of Preferred Stock

Our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval, of which Series E Preferred Stock and Series E-1 Preferred Stock, or, collectively, the Preferred stock, is outstanding. Our board of directors may issue preferred stock in one or more series and has the authority to fix the designation and powers, rights and preferences and the qualifications, limitations, or restrictions with respect to each class or series of such class

without further vote or action by the stockholders. The ability of our board of directors to issue preferred stock without stockholder approval could have the effect of delaying, deferring or preventing a change of control of us or the removal of existing management.

Each share of the Series E Preferred Stock and Series E-1 Preferred Stock has a par value of $0.01 per share and a stated value equal to $1,000, or the Stated Value, and is convertible at any time at the option of the holder into the number of shares of common stock determined by dividing the stated value by the conversion price of $23.04, subject to certain limitations and adjustments, or the Conversion Price. Except for certain adjustments, the holders of Preferred Stock will be entitled to receive dividends on shares of Preferred Stock equal (on an as if converted basis) to and in the same form as dividends paid on shares of the common stock. Any such dividends that are not paid to the holders of Preferred Stock will increase the Stated Value. No other dividends will be paid on shares of Preferred Stock. The Preferred Stock will vote on an as converted basis on all matters submitted to the holders of common stock for approval, subject to certain limitations and exceptions. The affirmative vote of the holders of a majority of the then outstanding shares of Preferred Stock is required to increase the number of authorized shares of Preferred Stock or to alter or change adversely the powers, preferences or rights given to the Preferred Stock, or to amend the Company's organizational documents in any manner that adversely affects the rights of the holders of the Preferred Stock. Upon any liquidation of the Company, the holders of Preferred Stock will be entitled to receive out of the assets of the Company an amount equal to the Stated Value plus any accrued and unpaid dividends thereon for each share of Preferred Stock before any distribution or payment will be made to the holders of the common stock.

Reset Provisions

Pursuant to the terms of the Preferred Stock, the Conversion Price of the Preferred Stock was initially subject to adjustment in each of the following circumstances: (i) on the third trading day following the date that the Company effects a reverse stock split, or the Reverse Split Reset Date, (ii) the date that the initial registration statement covering the shares of common stock issuable upon the conversion of the Preferred Stock is declared effective by the SEC, or the Registration Reset Date, and (iii) in the event that all of the shares of common stock which we were required to register with the SEC were not then registered on an effective registration statement, the date that all of the shares underlying the respective Preferred Stock may be sold pursuant to Rule 144, or the Rule 144 Reset Date, each of such reset dates, a Reset Date and, collectively, the Reset Dates. On each Reset Date, the Conversion Price was to be reduced, and only reduced, to equal the lesser of (x) the then effective Conversion Price, and (y) 90% of the average of the five daily volume weighted average prices of the common stock immediately prior to each Reset Date, or the Reset Formula. From the date of issuance of the Preferred Stock until such time that the Company's common stock is listed or quoted on a national exchange, the Conversion Price is subject to price-based anti-dilution protections.

EXHIBIT 31.1

Certification
of Principal Executive Officer
Pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act

I, Jennifer K. Simpson, certify that:

1) I have reviewed this annual report on Form 10-K of Delcath Systems, Inc;

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

DATE
March 25, 2020

/s/ Jennifer K. Simpson
Jennifer K. Simpson
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

Certification
of Principal Financial Officer
Pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act

I, Barbra C. Keck, certify that:

1) I have reviewed this annual report on Form 10-K of Delcath Systems, Inc;

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

DATE
March 25, 2020

/s/ Barbra C. Keck
Barbra C. Keck
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32.1

Certification Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes –Oxley Act of 2002

In connection with the Annual Report on Form 10-K of DELCATH SYSTEMS, INC. (the "Company") for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jennifer K. Simpson, the President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

DATE
March 25, 2020

/s/ Jennifer K. Simpson
Jennifer K. Simpson
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

Certification Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes –Oxley Act of 2002

In connection with the Annual Report on Form 10-K of DELCATH SYSTEMS, INC. (the "Company") for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Barbra C. Keck, the Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

DATE
March 25, 2020

/s/ Barbra C. Keck
Barbra C. Keck
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)